Nos. 24-1820 & 24-1821

United States Court of Appeals for the Third Circuit

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey, Nos. 3:23-cv-03335 & 3:23-cv-03818

JOINT APPENDIX VOLUME 1
(JA1-JA32)

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, NY 10281

Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102

Counsel for Plaintiff-Appellant Bristol Myers Squibb Company

Noel J. Francisco
Yaakov M. Roth
Brett A. Shumate
Charles E.T. Roberts
John Henry Thompson
Louis J. Capozzi III
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
(202) 879-3939

Robert A. Long, Jr.
Kevin F. King
Michael M. Maya
Bradley K. Ervin
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

Counsel for Plaintiff-Appellant Janssen Pharmaceuticals, Inc.

[additional counsel listed on inside cover]

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
MICHAEL S. RAAB
LINDSEY POWELL
STEVEN A. MYERS
DAVID L. PETERS
CATHERINE PADHI
Attorneys, Appellate Staff
Civil Division, Room 7712
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-5091

Counsel for Defendants-Appellees

TABLE OF CONTENTS

Date Filed	Document	ECF No.	Page
Volume 1 of 3			
4/29/2024	Opinion, *Bristol Myers Squibb Co. v. Becerra*, No. 3: 23-cv-03335, and *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JBD (D.N.J. Apr. 29, 2024)	110 (*BMS*) 98 (*Janssen*)	JA1
4/29/2024	Order Denying Motion for Summary Judgment and Granting Cross-Motion for Summary Judgment, *Bristol Myers Squibb Co. v. Becerra*, No. 3: 23-cv-03335, and *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JBD (D.N.J. Apr. 29, 2024)	111 (*BMS*) 99 (*Janssen*)	JA27
4/29/2024	Notice of Appeal (Bristol Myers Squibb Company)	113 (*BMS*)	JA29
4/30/2024	Notice of Appeal (Janssen Pharmaceuticals, Inc.)	100 (*Janssen*)	JA31
Volume 2 of 3			
	Docket Sheet, *Bristol Myers Squibb Company v. Becerra*		JA33
6/16/2023	Complaint, *Bristol Myers Squibb Company v. Becerra*	1 (*BMS*)	JA52
8/16/2023	Declaration of Christopher T. Mancill in Support of Plaintiff's Motion for Summary Judgment	36-1	JA82
8/16/2023	Declaration of Toni-Ann Citera in Support of Plaintiff's Motion for Summary Judgment	36-2	JA96
8/16/2023	Citera Decl. Ex. A: *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, CMS (June 30, 2023)	36-2	JA99

Date Filed	Document	ECF No.	Page
8/16/2023	Citera Decl. Ex. B: Medicare Drug Price Negotiation Program Agreement	36-2	JA298
8/16/2023	Citera Decl. Ex. C: *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*, CMS (Mar. 15, 2023)	36-2	JA311
8/16/2023	Citera Decl. Ex. D: S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation*, 2026-2028, 29 JMCP 229 (Mar. 2023)	36-2	JA403
Volume 3 of 3			
	Docket Sheet, *Janssen v. Becerra*		JA411
7/18/2023	Complaint, *Janssen v. Becerra*	1 (*Janssen*)	JA429
8/16/2023	Declaration of Jeff Chiesa in Support of Plaintiff's Motion for Summary Judgment	30-2	JA474
8/16/2023	Chiesa Decl. Ex. A: CMS Document, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2025"	30-3	JA477
8/16/2023	Chiesa Decl. Ex. B: Medicare Drug Price Negotiation Program Agreement	30-4	JA676
8/16/2023	Chiesa Decl. Ex. C: Study by Sean Dickson and Dr. Inmaculada Hernandez, "Drugs Likely Subject to Medicare Negotiation 2026–2028"	30-5	JA689
8/16/2023	Chiesa Decl. Ex. D: Congressional Research Service report, "Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)"	30-6	JA697

Date Filed	Document	ECF No.	Page
8/16/2023	Chiesa Decl. Ex. E: Joint Committee on Taxation November 2021 publication, "Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The 'Build Back Better Act,' As Passed By The House of Representatives: Fiscal Years 2022–2031"	30-7	JA735
8/16/2023	Chiesa Decl. Ex. F: Congressional Budget Office 2022 publication, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act"	30-8	JA746
8/16/2023	Chiesa Decl. Ex. G: Testimony of CMS Administrator Brooks-LaSure before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health	30-9	JA786
8/16/2023	Declaration of Blasine Penkowski in Support of Janssen's Motion for Summary Judgment	30-10	JA791

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB COMPANY, Plaintiff, v. **XAVIER BECERRA, *et al.***, Defendants.	Civil Action No. 23-3335 (ZNQ) (JBD) **OPINION**
JANSSEN PHARMACEUTICALS, INC., Plaintiff, v. **XAVIER BECERRA, *et al.***, Defendants.	Civil Action No. 23-3818 (ZNQ) (JBD)

QURAISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiff Bristol Myers Squibb Company ("BMS") and Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen") (collectively, "Plaintiffs") each filed a Motion for Summary Judgment. ("BMS's Motion", ECF No. 36; "Janssen's Motion", ECF No. 30) (collectively, "Plaintiffs' Motions for Summary Judgment"). Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services ("HHS"), Centers for Medicare & Medicaid Services ("CMS"), and Ananda V. Burra (collectively, "Defendants") filed Cross-Motions for Summary Judgment

("Defendants' Cross-Motion for Summary Judgment") against BMS (ECF No. 38) and Janssen (ECF No. 33.) The Court has under consideration the following submissions:[1]

- BMS's brief in support of its Motion. ("BMS Moving Br.", ECF No. 36-3.)
- Janssen's brief in support of its Motion. ("Janssen Moving Br.", ECF No. 30-1.)
- Defendants' combined brief in opposition to Plaintiffs' Motions and in support of their Cross-Motion. ("Defs.' Cross-Br.", ECF No. 38-1.)[2]
- BMS's combined brief in opposition to Defendants' Cross-Motion and reply in support of its Motion. ("BMS's Resp. Br.", ECF No. 80.)
- Janssen's combined brief in opposition to Defendants' Cross-Motion and reply in support of its Motion. ("Janssen's Resp. Br.", ECF No. 71.)
- Defendants' reply in support of their Cross-Motion. ("Defs.' Reply Br.", ECF No. 84.)[3]

The Court has carefully considered the parties' submissions and held oral argument on March 7, 2024 ("Oral Arg. Tr.", ECF No. 107). For the reasons set forth below, the Court will GRANT Defendants' Cross-Motions for Summary Judgment and DENY Plaintiffs' Motions for Summary Judgment.

I. BACKGROUND AND PROCEDURAL HISTORY

A. GENERAL BACKGROUND

This action arises out of BMS and Janssen's claims challenging the constitutionality of the Drug Price Negotiation Program ("Program") created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169 ("IRA"). *See* 42 U.S.C. § 1320f *et seq.* In considering a challenge against the Program brought by Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB, our sister court in Delaware carefully and meticulously provided a general background of the Program. *See*

[1] There are also several amicus briefs filed in both cases. The amici include: Fresenius Kabi USA, LLC, Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA, AARP and AARP Foundation, Intellectual Property Law And Health Law Scholars, American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology, Constitutional Accountability Center, Economists and Scholars of Health Policy, Abrams Institute for Freedom of Expression, Alliance for Aging Research, and Nationally Recognized Healthcare and Medicare Experts.
[2] Defendants filed identical Cross-Briefs against BMS and Janssen, ECF Nos. 38-1 and 33-1, respectively. For the purpose of this Opinion, the Court cites to the brief filed at ECF No. 38-1.
[3] Defendants similarly filed identical Reply briefs against BMS and Janssen, ECF Nos. 84 and 75, respectively. For the purpose of this Opinion, the Court cites to the brief filed at ECF No. 84.

AstraZeneca Pharms. LP v. Becerra, Civ. No. 23-931, 2024 WL 895036, at *1–5 (D. Del. Mar. 1, 2024) (explaining the history, enactment, and functions of the Program). Given the thoroughness of the court's factual background, and for judicial economy, this Court incorporates by reference the background of the Program set forth by the Delaware District Court.

B. PLAINTIFF SPECIFIC BACKGROUND & PROCEDURAL HISTORY

BMS initiated this action by filing a Complaint on June 16, 2023. ("BMS Compl.", ECF No. 1.) Janssen filed its Complaint on July 18, 2023. ("Janssen Compl.", ECF No. 1.) BMS and Janssen are both pharmaceutical manufacturers with their principal place of business in New Jersey. (BMS Compl. ¶ 11; Janssen Compl. ¶¶ 17–18.) Among other medications, BMS manufactures and sells Eliquis; Janssen manufactures and sells Xarelto. (BMS Compl. ¶ 12; Janssen Compl. ¶ 18.) Both medicines are used to prevent blood clots and reduce the risk of strokes. (BMS Compl. ¶ 12; Janssen Compl. ¶ 18.) Notably, Eliquis and Xarelto are both subject to the first round of Program as "negotiation eligible" drugs.[4] (BMS Compl. ¶ 12; Janssen Compl. ¶ 77.)

BMS and Janssen allege three claims in their Complaints. First, Plaintiffs allege that the Program is an uncompensated physical taking of personal property in violation of the Fifth Amendment's Taking Clause ("Takings Clause claim"). (BMS Compl. ¶¶ 93–101; Janssen Compl. ¶¶ 129–39). Next, Plaintiffs allege that the Program compels their speech in violation of the First Amendment ("Compelled Speech claim"). (BMS Compl. ¶¶ 102–07; Janssen Compl. ¶¶ 140–49.) Finally, Plaintiffs allege that the Program is an unconstitutional condition on Medicare and Medicaid participation.[5] (BMS Compl. ¶ 88; Janssen Compl. ¶¶ 150–55.)

[4] To be consistent with the language of the Program, for the purposes of this Opinion, the Court will use the term "drug" or "drugs" to refer to Eliquis and Xarelto.
[5] For the purposes of this Opinion, the Court uses the term Medicare when it refers to both Medicare and Medicaid.

Plaintiffs and Defendants in both cases have "conferred, and agree that these cases present sufficiently similar legal questions about the constitutionality of a federal statute that can—and should—be resolved through coordinated dispositive motions, without the need for discovery." (ECF No. 34 at 1.) Accordingly, the Court dispensed with any submission of statements of disputed facts by the parties given they are strictly challenging the constitutionality of the Program. (ECF No. 35.)

II. JURISDICTION

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

III. LEGAL STANDARD

A motion for summary judgment may be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). If there is "no genuine dispute over material facts," then courts "will order judgment to be entered in favor of the party deserving judgment in light of the law and undisputed facts." *Iberia Foods Corp. v. Romeo*, 150 F.3d 298 (3d Cir. 1998).

IV. DISCUSSION[6]

The Court will address the following three issues raised by the parties. First, the Court will consider whether the Program is a physical taking in violation of the Fifth Amendment's Taking Clause. Next, the Court will consider whether the Program compels speech in violation of the First Amendment. Finally, the Court will consider whether the Program violates the unconstitutional conditions doctrine.

[6] Given the substantial similarity between BMS and Janssen's legal claims, arguments, and briefs, for the purpose of this Opinion, the Court will primarily cite to the briefs filed by BMS.

A. FIFTH AMENDMENT TAKINGS CLAUSE CLAIM

1. Parties' Positions

a) Plaintiffs

Plaintiffs' main position is that the Program effects a physical taking of Plaintiffs' drugs in violation of the Fifth Amendment. (BMS Moving Br. at 12.) Plaintiffs argue that their drugs are private property protected by the Takings Clause. (*Id.* at 24; Janssen Moving Br. at 26.) Next, Plaintiffs claim that the Program is not "a mere price cap" but rather a "forced transfer dressed up as a 'sale.'" (BMS Moving Br. at 13, 16.) Accordingly, Plaintiffs contend that "the Program's forced sales are functionally equivalent to physically seizing the medicine from the warehouse." (BMS Resp. Br. at 4.) Ultimately, Plaintiffs assert that "[t]he whole point of [the Program] is for the Government to avoid paying just compensation by paying far less than the fair market price" for the selected drugs. (BMS Moving Br. at 14–15.)

Plaintiffs explain that this compelled transfer occurs through the following scheme. First, pharmaceutical companies, like Plaintiffs, that are selected to participate in the Program must comply and agree to sell the selected drugs at the maximum fair price. (*Id.* at 7.) If Plaintiffs do not agree with the maximum fair price and want to sell the selected drug to Medicare at a different price, then Plaintiffs will incur a very high tax[7] on all of their drug sales from all sources. (*Id.* at 8.) Second, the only way a manufacturer could avoid the tax is if they withdraw from all Medicare sales entirely.[8] (BMS Resp. Br. at 6.) Finally, even if Plaintiffs withdraw from selling to

[7] The parties view the excise tax differently. Plaintiffs' position is that the excise tax starts at 186% and can go up to 1900% . (*See* BMS Moving Br. at 8.) In contrast, Defendants claim that the excise tax is 95%. (*See* BMS Moving Br. at 8.)

[8] Plaintiffs claim that they could not withdraw from the Program within adequate time to avoid the tax because the Program requires a manufacturer to give at least 11 months, and as many as 23 months, notice of termination; this deadline would have been January 2022, months before the Program was even enacted. (BMS Moving Br. at 32.) Defendants explain that there two ways in which Defendants can still withdraw from the Program. First, Defendants explained that under the 11-to-23-month statutory period, Plaintiffs remain eligible to file their notice of termination by "no later than January 30th, 2025 to be out of Medicare in time for the first sales that are actually subject to the

Medicare, it would not defeat their argument the Program is still a physical taking under Supreme Court precedent set by *Horne v. Department of Agriculture*, 576 U.S. 350 (2015). Plaintiffs argue that just because this forced transfer is "dressed-up" as a sale does not protect it from a Takings Clause claim. (BMS Moving Br. at 13.)

b) Defendants

In contrast, Defendants argue that the Program is not a physical taking and Plaintiffs incorrectly characterize it as a forced transfer. Instead, Defendants underscore that "neither the [Program] nor any other part of Medicare 'legally compel[s]' manufacturers to negotiate with CMS or sell their drugs to Medicare beneficiaries." (Defs.' Cross-Br. at 11 (quoting *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023))). For a claim to be valid under the Takings Clause, a property owner must be "legally compelled" to participate in a price-regulated activity. (*Id.* at 12, 19.) Here, pharmaceutical manufacturers can "opt out" of the Program in several ways, including (1) fully divesting "their interests in the drugs subject to negotiation before 2026" or (2) withdrawing from the Medicare markets. (*Id.* at 2.)

Instead, Defendants argue that participation in Medicare is voluntary. (*Id.* at 12 (quoting *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991))). Further, Defendants explain that the Program is a "valid exercise of Congress's constitutional authority to control the government's spending as a market participant." (*Id.* at 11.)

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maximum fair price." (Oral Arg. Tr. 61:22–62:6.) Second, pursuant to CMS's Revised Guidance, the HHS Secretary can terminate a manufacturer's agreement "before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue." (Defs.' Cross-Br. at 7.) Defendants also explained that a manufacturer can satisfy the good cause requirement under the second method of withdrawal by simply expressing their desire to no longer participate in the Program. (Oral Arg. Tr. 62:19–23.)

Defendants distinguish *Horne* on the basis that Plaintiffs in this case can avoid the statutory regime. Defendants explain that unlike the plaintiffs in *Horne*, Plaintiffs can sell their drugs to the wider market at their discretion if they do not choose to participate in the Program. Defendants also note that no statutory provision requires entities to sell their property to a government, especially when the government is acting as a market participant. (*Id.* at 12–13.) As such, when the government determines the price it is willing to pay, or "imposes caps on the amount the government will reimburse," the government "deprives [entities] of no property interest for the purposes of the Fifth Amendment." (*Id.* at 13.)

Further, Defendants argue that when Congress enacted the IRA, it did so pursuant to its powers under the Spending Clause, which "operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions.'" (*Id.*; quoting *Cummings v. Premier Rehab Keller, PLLC*, 142 S. Ct. 1562, 1570 (2022)). Finally, Defendants contend that Plaintiffs' argument that they cannot withdraw from the programs are "academic" because neither Plaintiff has expressed intent to withdraw from the program. (*Id.* at 15.)

2. Analysis

The Fifth Amendment's Takings Clause prohibits the government from taking private property for public use without just compensation. *River Valley Heights Corp. v. Twp. of W. Amwell*, Civ. No. 21-2042, 2023 WL 1433634, at *2 (3d Cir. Feb. 1, 2023); *see also* U.S. Const. amend. V. ("nor shall private property be taken for public use, without just compensation"). "The paradigmatic taking requiring just compensation is a direct government appropriation . . . of private property." *Horne*, U.S. at 358 (quoting *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537 (2005)). Requirements that a private owner "reserve" portions of their personal property for the use of the government are a "clear physical taking." *Id.* at 361. Property owners subject to a reserve requirement "lose the entire 'bundle' of property rights in the appropriated [property]—

'the rights to possess, use and dispose of' them." *Id.* at 361–62 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 432 (1982)).

The fact that a property owner may be entitled to net proceeds from a sale of their physical property "does not mean there has been no physical taking," particularly when the value of any contingent interest in the property is at the "discretion of the taker." *Id.* at 363. The government's "categorical duty to pay just compensation" upon a governmental taking remains the same whether applied to government appropriation of personal property or real property. *Id.* at 358. Historically, patents have received the same protection in federal courts as other types of property. "[A patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser." *Id.* at 359–60 (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)).

Although courts have devised formulas and structures for evaluating claims under the Fifth Amendment, "[t]here is no abstract or fixed point at which judicial intervention under the Takings Clause becomes appropriate." *Andrus v. Allard*, 444 U.S. 51, 65 (1979). "Resolution of each case . . . ultimately calls as much for the exercise of judgment as for the application of logic." *Id.*

The Court's analysis of Plaintiffs' Taking Clause claim takes place in two stages. First, the Court addresses whether the Program constitutes a physical taking in violation of the Fifth Amendment. Second, the Court addresses whether Plaintiffs' participation in the Program is voluntary.

a) The Program is Not a Physical Taking

The crux of Plaintiffs' principal argument is that the Program is a physical taking. To support their position, Plaintiffs rely heavily on the Supreme Court's decision in *Horne*. 576 U.S. 350 (2015).

The Horne family were raisin growers and handlers. *Id.* at 356. Under the United States Department of Agriculture's California Raisin Marketing Order, the Hornes, like all growers and handlers, were required to set aside a percentage of their crop for the government's use. *Id.* at 354. The government would not pay for this reserve, and it could choose to sell, allocate, or otherwise dispose of the reserved raisins. *Id.* The Raisin Administrative Committee (the "Raisin Committee") determined the allocation to be set aside, and then acquired title to the reserve raisins. *Id.*

Under the Marketing Order, raisins were sold "in noncompetitive markets . . . to exporters, federal agencies, or foreign governments" or the government "donate[d] them to charitable causes; release[d] them to growers who agree to reduce their raisin production; or dispose[d] of them by any other means consistent with the raisin program." *Id.* at 355 (internal quotation omitted). The growers retained a contingent interest in the raisins, and if they were sold, the growers received the net proceeds of the sales from the Raisin Committee. *Id.* at 363. Notably, in the years examined by the Supreme Court in *Horne*, the proceeds were either less than the cost of the production of the raisins or there were no proceeds at all. *Id.* at 355.

If growers, like the Hornes, did not create a raisin reserve for the government, they were assessed a fine "equal to the market value of the missing raisins." *Id.* at 356. In the Hornes' case, they refused to set aside a raisin reserve, and when trucks sent by the government came to pick up the raisins, the trucks were turned away. *Id.* The Hornes were then assessed the fine, upon which they proceeded to federal court. *Id.* Neither side in *Horne* contested that the government would have been within its powers to entirely bar the Hornes from growing raisins in the first place. *Id.* at 362.

Ultimately, the Supreme Court held that the "reserve requirement imposed by the Raisin Committee is a clear physical taking" and that the Takings Clause applied as much to personal property as it did to real property. *Id.* at 361. The Court explained that "[t]he Government's formal demand that the Hornes turn over a percentage of their raisin crop without charge, for the Government's control and use, is 'of such a unique character that it is a taking without regard to other factors that a court might ordinarily examine.'" *Id.* at 362 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 426–35 (1982)). The Court further held "[t]he fact that the growers retain a contingent interest of indeterminate value [in the reserve raisins] does not mean there has been no physical taking." *Id.* at 363. The Court also observed that this physical taking made the *Horne* case entirely distinct from cases focused on the regulation of sales. *Id.* at 362. Though "a physical taking of raisins and a regulatory limit on production may have the same impact on a grower," the "Constitution . . . is concerned with means as well as ends." *Id.* By requiring that growers set aside portions of their crop without paying just compensation, the government transgressed its powers under the Fifth Amendment. *Id.* at 363. Finally, the requirement to relinquish "specific, identifiable property as a 'condition' on permission to engage in commerce effects a per se taking." *Id.* at 365 (internal quotations omitted). The fact that the Hornes chose to participate in the raisin market was not a defense against the taking, and the Court held that it could not "reasonably be characterized as part of a . . . voluntary exchange . . . for the 'benefit' of being allowed to sell" the remaining raisin crop. *Id.* at 366.

Unfortunately for Plaintiffs in this case, *Horne* is inapposite to their plight for several reasons. Unlike *Horne*, there is no physical appropriation taking place and, setting aside their factual arguments, Plaintiffs fail to show how they are being *legally* compelled to participate in the Program.

Various sections of the Program explain that manufacturers and CMS engage in negotiations to determine "a maximum fair price for such selected drug of the manufacturer *in order for the manufacturer to provide access to such [maximum fair] price* . . . ." 42 U.S.C. § 1320f-2(a)(1), (a)(2), (a)(3) (emphasis added). Plaintiffs claim that the "Program's forced sales are functionally equivalent to physically seizing" the drug because the Program obligates the transfer of drugs to "Medicare at rates the Government dictates and to which [Plaintiffs] would never ordinarily agree." (BMS Resp. Br. at 4–5.) Plaintiffs also contend that to "provide 'access' to the 'maximum fair price'" for the drug, Plaintiffs "must physically provide [the drug] at that price." (*Id.* at 7.) In other words, "[y]ou can't have access to a price without access to a [drug]." (Oral Arg. Tr. 19:6–7.) Defendants, however, characterize Plaintiffs' interpretation of the Program as "a fairly thin read on which to infer that actual commercial transactions need to take place at that price." (*Id.* 59:12–14.) Pointing to § 1320f-6 of the Program, Defendants explain that it creates an "if-then" relationship: if a manufacturer sell a drug, then the manufacturer can only charge a price at or below the negotiated maximum fair price for that drug. (*Id.* 60:6–12.)

Despite Plaintiffs' attempts to liken the Program to the reserve requirement in *Horne*, the two are markedly different. Plaintiffs in this case distort their position to liken it to the passive role of the raisin growers who are *required* to "give a percentage of their crop to the Government, free of charge" by way of an agricultural regulatory program marketing order. *Horne*, 576 U.S. at 354. The regulatory program in *Horne* markedly differs in that it "regulated all sales of raisins on the open market" and compelled raisin growers to set aside reserve raisins for the government's use if growers sold their raisins at all. (Oral Arg. Tr. at 67:4–5.) Thus, Plaintiffs' reliance on *Horne* strategically overlooks the obvious point that the only way for raisin growers to avoid the reserve requirement was to stop selling raisins altogether. *Horne*, 576 U.S. at 365. That is not the

case here. The Program applies solely to sales to Medicare. There is no statutory provision that imposes a requirement that pharmaceutical manufacturers must set aside, keep, or otherwise reserve any of their drugs for the government's use, for the use of Medicare beneficiaries, or any other entity's use. Nor, as Plaintiffs conceded at oral argument, does the Program require a manufacturer to physically transmit or transport drugs at the agreed price. (Oral Arg. Tr. 58:12–13.)

Plaintiffs repeatedly highlight the tax penalties that a manufacturer will incur if it does not sell the drug at the agreed price.[9] However, as they also admitted at oral argument, Plaintiffs are free to opt out of Medicare entirely and sell their drugs to anyone but the government, or to divest their interest in the selected drug, or to remain in the Program but not make any sales to Medicare. (*Id.* 72:4–6.)

Plaintiffs separately argue that the Program is a Fifth Amendment violation under the *per se* takings rule expressed in *Cedar Point Nursery v. Hassid*. 594 U.S. 139 (2021). According to their theory, "a 'classic' or *per se* taking occurs when the Government forces a property owner to transfer possession or title, whether to 'itself or someone else.'" (BMS Moving Br. at 13 (quoting *Cedar Point*, 594 U.S. at 146). The statutory access to their drug at specific prices set by the government, in their view, "forces" the manufacturers to transfer the selected drugs "to those third parties at the price demanded by the Government—[the manufacturers] cannot refuse to deal on those terms." (*Id.* at 24.)

[9] Janssen relies on *Horne* for the proposition that legal compulsion is not required to establish a constitutional violation. (Janssen Resp. Br. at 2.) And, even if legal compulsion was required, Plaintiffs contend that they have satisfied that showing because the Program compels Plaintiffs to "comply with the Program's requirements for at least a minimum period or else pay the excise tax." (*Id.* at 2–3.) However, as the Court explained, there are still several opportunities for Janssen to withdraw from the Program and avoid any excise tax.

Cedar Point Nursery is another agricultural case. The eponymous nursery grew strawberries. 594 U.S. at 144. At issue was whether a state labor relations board regulation effected an impermissible taking because it provided a "right of access to union organizers to the premises of an agricultural employer for the purpose of meeting and talking with employees and soliciting their report." 594 U.S. at 144 (quoting Cal. Code Regs., tit. 8, § 20900(e).) The Supreme Court succinctly clarified that the "essential question" underlying a physical takings claim is "whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property." 594 U.S. at 149. Here, the Program neither requires nor forces Plaintiffs to give or sell their drugs to Defendants. As Defendants correctly note, the Program "does not authorize the government to requisition a manufacturer's drugs or other property. Nor does the IRA require a manufacturer to relinquish any drug it does not wish to sell." (Defs.' Cross-Br. at 2.) As such, the Court finds that the Program does not qualify as a *per se* taking under *Cedar Point*.

b) Plaintiffs' Participation in the Program is Voluntary

For their part, Defendants largely argue that the Program is not a taking because Plaintiffs' participation in the Program is voluntary. (*See generally* Defs.' Cross-Br; Defs.' Reply Br.) Plaintiffs disagree. Plaintiffs reiterate that their takings claim is premised on a physical taking, not a regulatory taking. (Oral Arg. Tr. 29:4–7.) Accordingly, Plaintiffs argue that because the Program effectuates a physical taking, it should not be treated as a condition on participation and the voluntariness principles set forth in *Horne* and *Valancourt Books, LLC v. Garland*, 82 F.4th 1222 (D.C. Cir. 2023), are applicable. (*Id.* 25:16–26:5.)

Before addressing Plaintiffs' narrow arguments specifically relating to the Program, the Court will first review the voluntary nature of participation in Medicare more broadly. As an initial matter, the parties have not identified any authority holding that participation in the

Medicare system is involuntary. (*See, e.g.*, *id.* 12:8–11 (The Court asked Plaintiffs if they had "found any case law in this circuit or any other that holds that the participation in the Medicare system is not voluntary?" and Plaintiffs responded, "No"). The Court, despite diligent efforts, was likewise unable to identify any such authority. If anything, the contrary appears true; at least one court of appeals has consistently held that participation by healthcare providers in Medicare is voluntary. *See Livingston Care Ctr., Inc. v. U.S.*, 934 F.2d 719, 720 (6th Cir. 1991) ("[P]articipation in the Medicare program is a voluntary undertaking."); *Baptist Hosp. East v. Sec'y of HHS*, 802 F.2d 860, 869–70 (6th Cir. 1986) ("[P]articipation in the Medicare program is wholly voluntary.").

More recently and more to the point, other district courts that have considered the same challenge to the Program have found that a manufacturer's participation in the Program is voluntary.[10] The Southern District of Ohio considered challenges to the Program in the context of an emergent preliminary injunction seeking to enjoin the implementation of the Program. *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *1. The district court stated that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (citing *Baptist Hosp.*, 802 F.2d 860 at 869). The court further found that "[a]s there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation." *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *11.

[10] There have been several challenges brought against the Program across various district courts. In this Opinion, the Court specifically refers to the district court decisions from the Southern District of Ohio in *Dayton Area Chamber of Com. v. Becerra*, Civ. No. 3:23-cv-156, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023), and the District of Delaware in *AstraZeneca Pharms. LP v. Becerra*, Civ. No. 23-931, 2024 WL 895036 (D. Del. Mar. 1, 2024). The Court clarifies that though the courts in *Dayton Area Chamber of Com.* and *AstraZeneca* did not address the identical constitutional challenges brought by Plaintiffs in the present action, the courts' findings regarding voluntariness are nevertheless relevant and applicable here.

More recently, as noted above, our sister court in Delaware heard another challenge to the Program. *AstraZeneca Pharms.*, 2024 WL 895036. It agreed with the Southern District of Ohio. In that case, plaintiff AstraZeneca Pharmaceuticals LP claimed, inter alia, that the Program violated its Fifth Amendment due process rights. *Id.* at *13. In relevant part, the district court found that "[n]either the IRA nor any other federal law requires AstraZeneca to sell its drugs to Medicare beneficiaries. On the contrary, 'participation in the Medicare program is a voluntary undertaking.'" *Id.* at *15 (quoting *Livingston Care Ctr.*, 934 F.2d at 720.)

Plaintiffs emphasize the "massive penalty" they would incur should they reject the maximum fair price. Plaintiffs argue that the government has total control over the market for pharmaceuticals and that "[c]ompletely withdrawing from almost half the domestic pharmaceutical market is not commercially feasible." (Janssen Moving Br. at 11.) Courts have roundly rejected such arguments. *See Baptist Hosp.*, 802 F.2d 860 at 869–70 ("If any provider fears that its participation will drive it to insolvency, it may withdraw from participation."); *Livingston Care Ctr.*, 934 F.2d 719, 721 (6th Cir. 1991) ("Providers of health care who choose to participate in the federally sponsored program for the aged and disabled do so with no guarantee of solvency. Just as those who choose to serve individuals not covered by Medicare assume the risks of the private market, those who opt to participate in Medicare are not assured of revenues.") (citation omitted); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary. This voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation . . . .).

Nonetheless, Plaintiffs are dismissive of the adverse case law. They argue that it is not applicable because the cases are (1) "outdated" given of the Supreme Court's decision in *Horne*, (2) "off-point" because the cases do not address schemes that resemble the Program, and (3) "limited" because they analyzed voluntariness in the context of Due Process and regulatory takings claims. (BMS Resp. Br. at 23–26.) Instead, Plaintiffs urge the Court to view the Program as a "physical taking backed by a penalty," not a condition, and to again find *Horne* instructive. (Oral Arg. Tr. 25:21–22.) To the extent Plaintiffs argue that *Horne* is instructive and that the Court should analyze the Program as a physical taking, the Court has already rejected that analogy.

Plaintiffs also point to *Valancourt*, a recent D.C. Circuit case finding that the "mandatory deposit requirement" of Section 407 of the Copyright Act was a physical taking in violation of the Takings Clause. 82 F.4th at 1231. Section 407 states that "the owner of copyright or of the exclusive right of publication in a work published in the United States shall deposit, within three months after the date of such publication . . . two complete copies of the best edition" of the work "for the use or disposition of the Library of Congress." *Id.* at 1227 (quoting 17 U.S.C. § 407(a)(1), (b)). A copyright owner who fails to make the "required deposit" faces several fines. *Id.* (citing 17 U.S.C. § 407(d)(1)–(2), (d)(3). The court of appeals held this constituted an impermissible taking. Notably, the court's decision is narrow, and in its own words "is tied to the particular circumstances" of Section 407. *Id.* at 1239.

Setting aside the express narrowness of the *Valancourt* decision, it is also readily distinguishable from Plaintiffs' case. The mandatory deposit requirement in *Valancourt*, like the reserve requirement in *Horne*, is part of a regime that parties could not readily exit. The court explained that when the deposit occurs, the copyright owners "lose the entire 'bundle' of property rights" in the copies and they "receive no additional benefit for the works they forfeit." *Id.* at

1231–32 (citations omitted). Further, the deposit requirement was enforced via a demand letter that did not indicate another "option other than surrendering the property at issue or paying a fine, and in which Valancourt had no indication from any other source of the existence of a costless option to disavow copyright protection and thereby avoid complying with the sole options described in the demand letter." *Id.* at 1239. The Program in this case bears none of these features.

Again, manufacturers selected to participate in the Program will not face any fee, tax, or fine if they initially choose not to participate in the Program. Despite Plaintiffs' attempts to frame their plight as such, their options go beyond either (1) participating in the Program or (2) paying a fine. There are alternatives for Plaintiffs to explore should they choose, including exiting from sales to Medicare in the first instance. Plaintiffs who do so can continue to sell their drugs to any purchaser other than the federal government. Selling to Medicare is a choice Plaintiffs can accept or not accept. This is true for any negotiation between a purchaser and a seller. The plaintiffs in *Horne* and *Valancourt* were never given that choice. Accordingly, there is no "obligatory legal framework" here that Plaintiffs can only exit by paying a fine. (Oral Arg. Tr. 69:6–20.)

Along these lines, there is a final distinguishing factor between the Program and the physical takings in the cases Plaintiffs cite. Plaintiffs contend that the Program taxes nonparticipating manufacturers and punishes private parties "by shutting them out of other markets," which is a "quintessential exercise of sovereign power." (BMS Resp. Br. at 20.) However, as Defendants correctly note, the Program is akin to other Medicare reimbursement limits, and reflects a valid exercise of Congress's constitutional authority to control the government's spending as a market participant. (Defs.' Cross-Br. at 11.) The Program is not regulating how the market operates, it arises in the context of Congress acting as a "proprietor of its own assets as opposed to regulating how a market is going to operate." (Oral Arg. Tr. 66:23–

67:2–3.) The government has the fundamental right to decide how it will spend taxpayer money. *South Dakota v. Dole*, 483 U.S. 203, 206–08. Likewise, Plaintiffs have the fundamental right to decide whether they want to sell their drug to a specific purchaser under the conditions set. Here, the Court is not persuaded by Plaintiffs' arguments that its participation in the Medicare program is involuntary. The Court agrees with the courts in the Southern District of Ohio, Delaware, and the established case law across several circuits holding that there can be no taking when participating in Medicare is voluntary and it rejects Plaintiffs' attempts to suggest otherwise.

In short, Defendants are not taking drugs from Plaintiffs. BMS and Janssen want to sell their drugs to Medicare, a significant (but not the sole) buyer of pharmaceuticals in the United States. Selling to Medicare may be less profitable than it was before the institution of the Program, but that does not make Defendants' decision to participate any less voluntary. For the reasons provided, the Court concludes that the Program does not result in a physical taking nor direct appropriation of Plaintiffs' drugs.

B. FIRST AMENDMENT COMPELLED SPEECH CLAIM

1. Parties' Positions

Plaintiffs argue that unconstitutional Compelled Speech begins when the Program forces them to engage in "sham 'negotiations'" that result in "faux 'agreements.'" (BMS Moving Br. at 21.) Once Plaintiffs sign the agreement, they are then forced to publicly express Defendants' preferred message that the resulting sales at below-market prices is "fair." (*Id.*) They point to the template "Medicare Drug Price Negotiation Program Agreement" ("Template Agreement") and argue that its use of certain terms such as "agreement," "negotiate," and "maximum fair price" re-enforces this message, which is driven by Defendants' political objectives. (*Id.*, Decl. of Toni-Ann Citera Ex. B, ECF No. 36-2.) Plaintiffs argue that the Program's agreements are more than

ordinary commercial contracts because they convey an implicit agreement by Plaintiffs that they are "negotiating" and an explicit agreement by Plaintiffs that the below-market maximum fair price is actually a "fair price." (*Id.* at 25.) Overall, Plaintiffs contend that the agreements suggest that Plaintiffs are "choosing to give the Government a massive break on the price" of the drugs, even though Plaintiffs insist they are not. (*Id.*)

Like with Plaintiffs' Takings Claim, Defendants argue that Plaintiffs' Compelled Speech claim fails because their participation in the Program is voluntary. Accordingly, Defendants contend that "because the Negotiation Program is entirely voluntary, it does not compel any manufacturer to do anything at all—either by signing an agreement or otherwise." (Defs,' Cross-Br. at 31.) Notwithstanding the voluntary nature of the Program, Defendants also argue that signing the agreements does not compel Plaintiff's speech because the Program regulates conduct, not speech. Additionally, Defendants argue that the agreements are not expressive "merely because they were written and *could* be incorrectly understood as conveying a message." (Defs.' Reply Br. at 40.) Defendants maintain that the Program's agreements are "purely commercial arrangements" that "exist solely to memorialize manufacturers' voluntary undertaking of a commitment to participate in the [Program]—and ultimately, to charge Medicare beneficiaries no more than the negotiated prices." (*Id.* at 37–38.)

2. Analysis

A threshold issue for their Compelled Speech claim is whether Plaintiffs are compelled to participate in the Program. Setting aside the broader issue of whether the Program itself constitutes speech for First Amendment purposes for the moment, the Third Circuit instructs that "a violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion." *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005). "In order to

compel the exercise . . . of speech, the governmental measure must punish, or threaten to punish, protected speech by governmental action that is 'regulatory, proscriptive, or compulsory in nature." *Id.* (quoting *Phelan v. Laramie Cnty. Cmty. Coll. Bd. of Trs.*, 235 F.3d 1243, 1244–47 (10th Cir. 2000)). At oral argument, Plaintiffs posited that the excise tax penalty is "what creates the First Amendment problem" and that if that penalty is stricken, then Plaintiffs no longer have a First Amendment claim. (Oral Ag. Tr. 124:4–9.) Like their Takings Clause claim, Plaintiffs' Compelled Speech claim is premised on the theory that the Program is inherently involuntary and that Plaintiffs do "*not* voluntarily agree" with any aspect of the Program. (BMS Moving Br. at 24.) However, for the reasons provided, the Court has already concluded that the Program is voluntary and that Plaintiffs are not being compelled or forced to participate in the Program. Accordingly, the Court rejects Plaintiffs' arguments that rely on involuntariness as the basis of their compelled speech claim.

a) The Program Regulates Conduct, Not Speech

First, contrary to Plaintiffs' interpretation, the Program regulates conduct, not speech. Any effect on Plaintiffs' speech in this case is merely incidental.[11]

"It is settled law that '[g]overnment action that . . . requires the utterance of a particular message favored by the Government, contravenes th[e] essential right' to refrain from speaking protected by the First Amendment." *Ridgewood Bd. of Educ.*, 430 F.3d at 187 (quoting *Turner Broad. Sys., Inc. v. F.C.C.*, 512 U.S. 622, 641 (1994)). "[L]eading First Amendment precedents have established the principle that freedom of speech prohibits the government from telling people

[11] Plaintiffs' own inconsistent positions as to the Program's purpose reflects their strained Compelled Speech claim. Initially, with respect to their Takings Cause claim, Plaintiffs argued that the Program mandated and compelled the transfer of the physical drugs themselves. In contrast, with respect to their Compelled Speech claim, Plaintiffs argue that the "only thing the statute mandates is the agreement, the speech, and then that is what gives rise to the obligation relating to pricing and conduct." (Oral Arg. Tr. 100:9–11.)

what they must say." *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 61 (2006). Separately, courts have also routinely found that a statute regulates "conduct, not speech" when it affects what someone "must *do* . . . [and] not what they may or may not *say*." *FAIR*, 547 U.S. at 60 (emphasis in original); *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011) ("It is true that restrictions on protected expression are distinct from restrictions on economic activity or, more generally, on nonexpressive conduct."). Plaintiffs claim that the Program "fits really neatly" into the pattern of First Amendment case law holding that the government cannot "compel a person to speak its own preferred messages," but the Court disagrees. (Oral Arg. Tr. 99:2–8; *303 Creative LLC v. Elenis*, 143 S. Ct. 2298, 2312 (2023)).

Plaintiffs point to *Expressions Hair Design v. Schneiderman* where the Supreme Court found a New York price regulation improperly regulated speech. 581 U.S. 37 (2017). The price regulation at issue, N.Y. Gen. Bus. Law § 518, prohibits merchants from imposing surcharges to customers who pay with a credit card but permits merchants to offer discounts to customers who pay with cash. *Id.* at 40. For example, if a merchant wants to sell an item for $10, the merchant can charge $10 to a buyer paying with cash. *Id.* at 47. However, if the merchant wants to charge a buyer paying with a credit card an additional 3% surcharge to account for a credit transaction fee, the merchant must convey that price as a single sticker price of $10.30 as opposed to "$10, with a 3% credit card surcharge." *Id.* On appeal, the Second Circuit concluded that § 518 did not violate the First Amendment because it regulated conduct, not speech. *Id.* at 46–47. The Second Circuit opined that "price controls regulate conduct alone" and that a "law regulating the relationship between two prices regulates speech no more than a law regulating a single price." *Id.* The Supreme Court agreed with the Second Circuit that "§ 518 regulates a relationship between a sticker price and the price charged to credit card users." *Id.* at 47–48. However, the Supreme

Court drew a different conclusion: "[i]n regulating the communication of prices rather than prices themselves, § 518 regulates speech." *Id.* at 48. The Supreme Court distinguished § 518 from a "typical price regulation" because the law does not simply regulate the amount of money a merchant could collect for a sale. *Id.* at 47. In that scenario, the law regulates the merchant's conduct and any "written or oral communications" the merchant uses to collect the money, such as identifying an item's price on a menu, are "only incidental to its primary effect on conduct." *Id.*

Critical to the holding in *Expressions*, though, is that § 518 "tells merchants nothing about the amount they are allowed to collect from a cash or credit card payer" but rather the law regulates how merchants communicate their prices. *Id.* Section 518 did not restrict what merchants could charge. Instead, the law constrained the ways that merchants could communicate their prices to buyers. The case before this Court is arguably the inverse of the one in *Expressions*. The primary purpose of the Program is to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare. The agreements and negotiations are incidental mechanisms the government is using to set those prices. In sum, the Court finds that the Program permissibly regulates Plaintiffs' commercial conduct, not their communication of information.

b) Signing the Program's Agreements does not Constitute Expressive Conduct

Plaintiffs' real issue, then, is with the terminology Congress used within the Program's agreements. Plaintiffs object to several terms used in the Template Agreement, including "negotiate," "agree," and "maximum fair price." Plaintiffs' key concern is that by agreeing to the final drug price, they are openly admitting that the price is the "maximum fair price." (BMS Resp. Br. at 30.) That "message" runs against Plaintiffs' sincere belief that the drug prices are not fair. Therefore, unlike a traditional price regulation that would merely communicate a price, Plaintiffs

contend that the agreements are expressive because they convey the government's preferred message. The Court, however, rejects Plaintiffs position for several reasons.

First, the Program's agreements are ordinary commercial contracts. Here, pharmaceutical manufacturers, like Plaintiffs, choose to participate in the Program. They accordingly execute the required contracts to confirm their agreement with Defendants. While it is true that the "creation and dissemination of information are speech for First Amendment purposes," Plaintiffs do not point to any authority supporting the proposition that a contract is expressive simply because it contains information. *Sorrell*, 564 U.S. at 570. Even Plaintiffs acknowledge that "many contracts do not express views or convey beliefs." (BMS Moving Br. at 25.) Nor do manufacturers' signatures on the agreements evidence any expressive conduct. Plaintiffs strain to analogize the impact of a manufacturer's signature on the Template Agreement to an individual's signature on a voting referendum. (BMS Resp. Br. at 33 (citing *John Doe No. 1 v. Reed*, 561 U.S. 186 (2010)). A voter's signature on a political petition, however, is unique because an "individual expresses a view on a political matter when he signs a petition." *Reed*, 561 U.S. at 194. "Even if the signer is agnostic as to the merits of the underlying law, his signature still expresses the political view that the question should be considered 'by the whole electorate.'" *Id.* at 195. Given that the Template Agreement itself is not expressive, the Court finds that a manufacturer's signature does not convey any message beyond its agreement with Defendants to the terms of the contract.

Importantly, the terms that Plaintiffs object to are statutory terms of art that are defined in the Program's statutory text. (Oral Arg. Tr. 107:21–108:9.) To accept Plaintiffs' position that the terminology used in the agreements forces Plaintiffs to convey a message requires construing the terms beyond the context of the agreement and beyond their statutorily defined meanings. As Defendants explained at oral argument, the terms are "ported over from the statute, they are defined

by the statute, and they are [in the agreements] to make clear that manufacturers are agreeing to abide—they are contracting to abide by the same technical understanding of these terms." (*Id.* 108:5–8.) The term "maximum fair price" is defined in § 1320f(c)(3). When "maximum fair price" is used in the agreements, its meaning reflects its statutorily defined definition, not a colloquial meaning of "maximum fair price." *See Meese v. Keene*, 481 U.S. 465, 484 (1987) ("It is axiomatic that the statutory definition of the term excludes unstated meanings of that term."). In *Meese*, the Supreme Court rejected a First Amendment challenge against a statute that used the term "political propaganda" as the statutory name to categorize certain films. *Id.* at 467. In holding that the term be interpreted by its statutory definition, the Supreme Court warned that legislation should be construed "as it is written, not as it might be read by a layman, or as it might be understood by someone who has not even read it." *Meese*, 481 U.S. at 485. Consistent with this guidance, the Court here similarly declines Plaintiffs' invitation to interpret the Program's terms beyond the scope of their statutory meaning.

Notably, nothing in the statute prevents Plaintiffs from publicly criticizing the Program or the final drug prices. Plaintiffs say they fear a "counternarrative" that they "would charge *more* than a 'fair' price for [the selected drugs] if not for the [Program's] mandated 'negotiations.'" (BMS Moving Br. at 26.) These, however, are public relations problems not constitutional problems.[12]

For the above reasons, the Court finds that the Program regulates conduct, not speech, and Plaintiffs are not engaging in expressive conduct by participating in the Program or by signing the

[12] Plaintiffs also claim that the disclaimer in the Template Agreement "does nothing to solve the compelled speech problem." (BMS Resp. Br. at 36.) Plaintiffs' argument assumes that the agreements are expressive and that the disclaimer is curing a potential compelled speech violation. However, the agreements are not expressive and the disclaimer clarifies that the "[u]se of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." (Template Agreement at 4.)

agreements. As a result, the Court does not address whether the Program survives First Amendment scrutiny. *Expressions*, 581 U.S. at 48.

C. UNCONSTITUTIONAL CONDITIONS DOCTRINE CLAIM

Having concluded that the Program is not a physical taking, that the Program does not compel Plaintiffs' speech, and that Plaintiffs' participation in the Program is voluntary, the Court next considers whether the Program violates the unconstitutional conditions doctrine.

Plaintiffs argue that, even if their participation in the Program were voluntary, the Program would still violate the unconstitutional conditions doctrine. They contend that the Program "is not immunized from constitutional scrutiny merely because it's labeled as a condition on participation in a voluntary program." (Oral Arg. Tr. 41:3-5.) Specifically, participating in the Program mandates Plaintiffs to (1) publicly endorse the government's preferred message, in violation of the First Amendment, and (2) transfer the right to access Eliquis and Xarelto to third parties on government-dictated terms, in violation of the Fifth Amendment. (BMS Moving Br. at 39.) These, Plaintiffs insist, represent unconstitutional conditions.

The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). Plaintiffs' doctrine claim suffers a fatal flaw: as Defendants succinctly observed at oral argument, "there's no constitutional right in danger of being trampled." (Oral Arg. Tr. 58:2–4.) "A predicate for any unconstitutional conditions claim is that the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing." *Koontz*, 570 U.S. at 612. Here, for the various reasons discussed, the Court has already found that the Program does *not* constitute a physical taking in violation of the Fifth Amendment, nor does the Program regulate speech or

compel Plaintiffs to convey any government message in violation of the First Amendment. *See, e.g.*, *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 210 (D.N.J. 2021), *rev'd in part on other grounds,* 58 F.4th 696 (3d Cir. 2023) ("To the extent that [plaintiff] has not established either a physical or regulatory taking under the Violation Letters, as I find here, the unconstitutional conditions doctrine is inapplicable."). On that basis, the Court finds the unconstitutional doctrine does not apply under these circumstances and declines to consider Plaintiffs' claim further.

V. CONCLUSION

For the reasons stated above, the Court will GRANT Defendants' Cross-Motions for Summary Judgment and DENY Plaintiffs' Motions for Summary Judgment. An appropriate Order will follow.

Date: April 29, 2024

Zahid. N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB COMPANY, Plaintiff, v. **XAVIER BECERRA, *et al.***, Defendants.	Civil Action No. 23-3335 (ZNQ) (JBD) **ORDER**
JANSSEN PHARMACEUTICALS, INC., Plaintiff, v. **XAVIER BECERRA, *et al.***, Defendants.	Civil Action No. 23-3818 (ZNQ) (JBD)

QURAISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiff Bristol Myers Squibb Company ("BMS") and Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen") (collectively, "Plaintiffs") each filed a Motion for Summary Judgment. ("BMS's Motion", ECF No. 36; "Janssen's Motion", ECF No. 30). Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services ("HHS"), Centers for Medicare & Medicaid Services ("CMS"), and Ananda V. Burra (collectively, "Defendants") filed Cross-Motions for Summary Judgment ("Defendants' Cross-Motion for Summary Judgment") against

BMS (ECF No. 38) and Janssen (ECF No. 33.) For the reasons set forth in the accompanying Opinion,

IT IS on this **29th** day of **April 2024,**

ORDERED that Defendants' Cross-Motion for Summary Judgment against BMS (ECF No. 38) and Defendants' Cross-Motion for Summary Judgment against Janssen (ECF No. 33) are hereby **GRANTED**; and it is further

ORDERED that Judgment is hereby entered for Defendants and against Plaintiffs as to all claims; and it is further

ORDERED that BMS's Motion (ECF No. 36) and Janssen's Motion (ECF No. 30) are hereby **DENIED**; and it is further

ORDERED that the Clerk is instructed to mark this matter **CLOSED**.

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE

SILLS CUMMIS & GROSS P.C.
Jeffrey J. Greenbaum
Katherine M. Lieb
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

JONES DAY
Toni-Ann Citera*
Rajeev Muttreja*
250 Vesey Street
New York, NY 10281
(212) 326-3939

*admitted *pro hac vice*

JONES DAY
Noel J. Francisco*
Yaakov M. Roth*
Brett A. Shumate*
Charles E.T. Roberts*
51 Louisiana Ave. NW
Washington, DC 20012
(202) 879-3939

Attorneys for Plaintiff
Bristol Myers Squibb Company

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB COMPANY,	:	Civil Action No. 23-3335(ZNQ)(JBD)
Plaintiff,	:	Hon. Zahid N. Quraishi
v.	:	Hon. J. Brendan Day
XAVIER BECERRA, U.S. Secretary of Health & Human Services; CHIQUITA BROOKS-LASURE, Administrator of Centers for Medicare & Medicaid Services; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES,	:	**NOTICE OF APPEAL**
Defendants.	:	

Pursuant to Federal Rules of Appellate Procedure 3(a)(1) and 4(a)(1)(B), Plaintiff Bristol Myers Squibb Company hereby appeals to the United States Court of Appeals for the Third Circuit from the final judgment entered on April 29, 2024. *See* ECF No. 110 (Opinion); ECF No. 111 (Order).

Respectfully submitted,

/s/ Jeffrey J. Greenbaum

Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-5430

Toni-Ann Citera*
Rajeev Muttreja*
JONES DAY
250 Vesey Street
New York, NY 10281
(212) 326-3939

Noel J. Francisco*
Yaakov M. Roth*
Brett A. Shumate*
Charles E.T. Roberts*
JONES DAY
51 Louisiana Avenue N.W.
Washington, DC 20012
(202) 879-3939

*admitted *pro hac vice*

Counsel for Plaintiff
Bristol Myers Squibb Company

Dated: April 29, 2024

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

JANSSEN PHARMACEUTICALS, INC., *Plaintiff*, v. XAVIER BECERRA, Secretary of Health and Human Services, *et al.*, *Defendants*.	Civil Action No. 23-cv-03818-ZNQ-JBD

NOTICE OF APPEAL

Pursuant to Federal Rule of Appellate Procedure 3(a)(1), notice is hereby given that Janssen Pharmaceuticals, Inc., plaintiff in the above-captioned case, appeals to the United States Court of Appeals for the Third Circuit from the Order and Final Judgment entered in this action on April 29, 2024 (ECF No. 98), and from all associated orders and opinions, including without limitation the Opinion entered on April 29, 2024 (ECF No. 99).

Respectfully submitted,

/s/ Jeffrey S. Chiesa

Jeffrey S. Chiesa
Ronald L. Israel
CHIESA SHAHINIAN & GIANTOMASI PC
105 Eisenhower Parkway
Roseland, NJ 07068
(973) 325-1500

Robert A. Long, Jr. (*pro hac vice*)
Kevin F. King (*pro hac vice*)
Bradley K. Ervin (*pro hac vice*)
MaKade C. Claypool (*pro hac vice*)
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001-4956
(202) 662-6000

Counsel for Plaintiff
Janssen Pharmaceuticals, Inc.

April 30, 2024

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2024, the foregoing was electronically filed with the Clerk of Court using the appellate CM/ECF system.

Dated: July 12, 2024

/*s*/ Jacob (Yaakov) M. Roth
Jacob (Yaakov) M. Roth

Counsel for Appellant Bristol Myers Squibb Co.

Nos. 24-1820 & 24-1821

United States Court of Appeals for the Third Circuit

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey, Nos. 3:23-cv-03335 & 3:23-cv-03818

JOINT APPENDIX VOLUME 2
(JA33-JA410)

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, NY 10281

Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102

Counsel for Plaintiff-Appellant Bristol Myers Squibb Company

Noel J. Francisco
Yaakov M. Roth
Brett A. Shumate
Charles E.T. Roberts
John Henry Thompson
Louis J. Capozzi III
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
(202) 879-3939

Robert A. Long, Jr.
Kevin F. King
Michael M. Maya
Bradley K. Ervin
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

Counsel for Plaintiff-Appellant Janssen Pharmaceuticals, Inc.

[additional counsel listed on inside cover]

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
MICHAEL S. RAAB
LINDSEY POWELL
STEVEN A. MYERS
DAVID L. PETERS
CATHERINE PADHI
Attorneys, Appellate Staff
Civil Division, Room 7712
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-5091

Counsel for Defendants-Appellees

TABLE OF CONTENTS

Date Filed	Document	ECF No.	Page
Volume 1 of 3			
4/29/2024	Opinion, *Bristol Myers Squibb Co. v. Becerra*, No. 3: 23-cv-03335, and *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JBD (D.N.J. Apr. 29, 2024)	110 (*BMS*) 98 (*Janssen*)	JA1
4/29/2024	Order Denying Motion for Summary Judgment and Granting Cross-Motion for Summary Judgment, *Bristol Myers Squibb Co. v. Becerra*, No. 3: 23-cv-03335, and *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JBD (D.N.J. Apr. 29, 2024)	111 (*BMS*) 99 (*Janssen*)	JA27
4/29/2024	Notice of Appeal (Bristol Myers Squibb Company)	113 (*BMS*)	JA29
4/30/2024	Notice of Appeal (Janssen Pharmaceuticals, Inc.)	100 (*Janssen*)	JA31
Volume 2 of 3			
	Docket Sheet, *Bristol Myers Squibb Company v. Becerra*		JA33
6/16/2023	Complaint, *Bristol Myers Squibb Company v. Becerra*	1 (*BMS*)	JA52
8/16/2023	Declaration of Christopher T. Mancill in Support of Plaintiff's Motion for Summary Judgment	36-1	JA82
8/16/2023	Declaration of Toni-Ann Citera in Support of Plaintiff's Motion for Summary Judgment	36-2	JA96
8/16/2023	Citera Decl. Ex. A: *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, CMS (June 30, 2023)	36-2	JA99

Date Filed	Document	ECF No.	Page
8/16/2023	Citera Decl. Ex. B: Medicare Drug Price Negotiation Program Agreement	36-2	JA298
8/16/2023	Citera Decl. Ex. C: *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*, CMS (Mar. 15, 2023)	36-2	JA311
8/16/2023	Citera Decl. Ex. D: S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation*, 2026-2028, 29 JMCP 229 (Mar. 2023)	36-2	JA403
Volume 3 of 3			
	Docket Sheet, *Janssen v. Becerra*		JA411
7/18/2023	Complaint, *Janssen v. Becerra*	1 (*Janssen*)	JA429
8/16/2023	Declaration of Jeff Chiesa in Support of Plaintiff's Motion for Summary Judgment	30-2	JA474
8/16/2023	Chiesa Decl. Ex. A: CMS Document, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2025"	30-3	JA477
8/16/2023	Chiesa Decl. Ex. B: Medicare Drug Price Negotiation Program Agreement	30-4	JA676
8/16/2023	Chiesa Decl. Ex. C: Study by Sean Dickson and Dr. Inmaculada Hernandez, "Drugs Likely Subject to Medicare Negotiation 2026–2028"	30-5	JA689
8/16/2023	Chiesa Decl. Ex. D: Congressional Research Service report, "Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)"	30-6	JA697

Date Filed	Document	ECF No.	Page
8/16/2023	Chiesa Decl. Ex. E: Joint Committee on Taxation November 2021 publication, "Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The 'Build Back Better Act,' As Passed By The House of Representatives: Fiscal Years 2022–2031"	30-7	JA735
8/16/2023	Chiesa Decl. Ex. F: Congressional Budget Office 2022 publication, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act"	30-8	JA746
8/16/2023	Chiesa Decl. Ex. G: Testimony of CMS Administrator Brooks-LaSure before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health	30-9	JA786
8/16/2023	Declaration of Blasine Penkowski in Support of Janssen's Motion for Summary Judgment	30-10	JA791

APPEAL,CLOSED

U.S. District Court
District of New Jersey [LIVE] (Trenton)
CIVIL DOCKET FOR CASE #: 3:23-cv-03335-ZNQ-JBD

BRISTOL MYERS SQUIBB COMPANY v. BECERRA et al
Assigned to: Judge Zahid N. Quraishi
Referred to: Magistrate Judge J. Brendan Day
Related Cases: 3:23-cv-14221-ZNQ-JBD
3:23-cv-20814-ZNQ-JBD
Case in other court: Third Circuit, 24-01820
Cause: 28:2201 Declaratory Judgment

Date Filed: 06/16/2023
Date Terminated: 04/29/2024
Jury Demand: None
Nature of Suit: 440 Civil Rights: Other
Jurisdiction: U.S. Government Defendant

Plaintiff

BRISTOL MYERS SQUIBB COMPANY represented by **JEFFREY J. GREENBAUM**
SILLS CUMMIS & GROSS P.C.
THE LEGAL CENTER
ONE RIVERFRONT PLAZA
NEWARK, NJ 07102-5400
(973) 643-7000
Email: jgreenbaum@sillscummis.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

KATHERINE MARGUERITE LIEB
SILLS CUMMIS & GROSS P.C.
101 PARK AVENUE
28TH FLOOR
NEW YORK, NY 10178
212-643-7000
Fax: 212-643-6500
Email: klieb@sillscummis.com
ATTORNEY TO BE NOTICED

JENNIFER LYNN DEL MEDICO
JONES DAY
250 Vesey Street
NEW YORK, NY 10281-1047
212-326-3658
Fax: 212-755-7306
Email: jdelmedico@jonesday.com
ATTORNEY TO BE NOTICED

V.

Defendant

XAVIER BECERRA represented by **BRIAN DAVID NETTER**
U.S. Secretary of Health & Human Services
DOJ-CIV

CIVIL DIVISION
950 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20530
202-514-2000
Email: brian.netter@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
U.S. DEPARTMENT OF JUSTICE
CIVIL DIVISION, FEDERAL
PROGRAMS BRANCH
1100 L STREET NW
WASHINGTON, DC 20005
202-305-8576
Email: stephen.pezzi@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ALEXANDER V SVERDLOV
DOJ-CIV
POC AGOSTINHO, JEAN
1100 L ST., N.W.
WASHINGTON, DC 20530
202-305-8550
Email: alexander.v.sverdlov@usdoj.gov
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
DOJ-CIV
DEPARTMENT OF JUSTICE
1100 L STREET NW
WASHINGTON, DC 20005
202-451-7729
Email: cassandra.m.snyder@usdoj.gov
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
DOJ-CIV
FEDERAL PROGRAMS BRANCH, CIVIL
DIVISION
1100 L ST. NW
WASHINGTON, DC 20005
202-880-0282
Email: christine.l.coogle@usdoj.gov
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
DOJ-USAO
DISTRICT OF NEW JERSEY
401 MARKET STREET
P.O. BOX 2098
CAMDEN, NJ 08101
856-757-5031

Fax: 856-757-5416
Email: heather.costanzo@usdoj.gov
ATTORNEY TO BE NOTICED

Defendant

CHIQUITA BROOKS-LASURE
Administrator of Centers for Medicare & Medicaid Services

represented by **BRIAN DAVID NETTER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ALEXANDER V SVERDLOV
(See above for address)
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
(See above for address)
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
(See above for address)
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

represented by **BRIAN DAVID NETTER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ALEXANDER V SVERDLOV
(See above for address)
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
(See above for address)
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
(See above for address)
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

CENTERS FOR MEDICARE & MEDICAID SERVICES

represented by **BRIAN DAVID NETTER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ALEXANDER V SVERDLOV
(See above for address)
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
(See above for address)
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
(See above for address)
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

ANANDA V. BURRA

represented by **BRIAN DAVID NETTER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

FRESENIUS KABI USA, LLC

represented by **JUSTIN TAYLOR QUINN**
ROBINSON MILLER LLC
IRONSIDE NEWARK
110 Edison Place, Suite 302
NEWARK, NJ 07102
973-690-5400
Email: jquinn@rwmlegal.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

PUBLIC CITIZEN

represented by **ANDREW M. MILZ**
FLITTER MILZ, P.C.
1814 EAST ROUTE 70
SUITE 350

CHERRY HILL, NJ 08003
856-396-0600
Fax: 833-775-3450
Email: amilz@consumerslaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

PATIENTS FOR AFFORDABLE DRUGS NOW represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

DOCTORS FOR AMERICA represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

PROTECT OUR CARE represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

FAMILIES USA represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

AARP
AARP Foundation
represented by **GLEN D. SAVITS**
GREEN SAVITS, LLC
25B VREELAND ROAD
SUITE 207
FLORHAM PARK, NJ 07932
(973) 695-7777
Fax: (973) 695-7788
Email: gsavits@greensavits.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

INTELLECTUAL PROPERTY LAW AND HEALTH LAW SCHOLARS represented by **JAMES E. CECCHI**
CARELLA BYRNE CECCHI BRODY & AGNELLO, P.C.
5 BECKER FARM ROAD
ROSELAND, NJ 07068
(973) 994-1700
Fax: (973) 994-1744
Email: jcecchi@carellabyrne.com

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

AMERICAN PUBLIC HEALTH ASSOCIATION

represented by **MADELINE GITOMER**
Democracy Forward
P.O. Box 34553
Washington, DC 20043
202-448-9090
Email: mgitomer@democracyforward.org
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

AMERICAN COLLEGE OF PHYSICIANS

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

SOCIETY OF GENERAL INTERNAL MEDICINE

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

AMERICAN GERIATRICS SOCIETY

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

AMERICAN SOCIETY OF HEMATOLOGY

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

NATIONALLY RECOGNIZED HEALTHCARE AND MEDICARE EXPERTS

represented by **JOHN W. LEARDI**
BUTTACI LEARDI & WERNER LLC
212 CARNEGIE CENTER
SUITE 202
PRINCETON, NJ 08540
609-799-5150
Fax: 609-799-5180
Email: jwleardi@buttacilaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

CONSTITUTIONAL ACCOUNTABILITY CENTER

represented by **DANIEL R. LEATHERS**
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP

250 HUDSON STREET
8TH FLOOR
NEW YORK, NY 10013
212-355-9500
Fax: 212-355-9592
Email: dleathers@lchb.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

LAW SCHOLARS represented by **DONALD A. ECKLUND**
CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.
5 BECKER FARM ROAD
ROSELAND, NJ 07068
(973) 994-1700
Fax: (973) 994-1744
Email: decklund@carellabyrne.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

ECONOMISTS AND SCHOLORS OF HEALTH POLICY
as Amici Curiae

represented by **JAMES C. SHAH**
MILLER SHAH LLP
2 HUDSON PLACE
SUITE 100
HOBOKEN, NJ 07030
856-526-1100
Fax: 866-300-7367
Email: jcshah@millershah.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ALEC BERIN
Miller Shah LLP
1845 Walnut Street
Suite 806
Philadelphia, PA 19103
610-891-9880
Fax: 866-300-7367
Email: ajberin@millershah.com
ATTORNEY TO BE NOTICED

Amicus

ABRAMS INSTITUTE FOR FREEDOM OF EXPRESSION

represented by **FLAVIO L. KOMUVES**
WEISSMAN & MINTZ LLC
220 DAVIDSON AVENUE
SUITE 410
SOMERSET, NJ 08873
732-563-4565
Email: fkomuves@weissmanmintz.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Alliance for Aging Research represented by **STEPHEN M. BALDINI**
AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.
ONE BRYANT PARK
NEW YORK, NY 10036
212-872-1000
Email: sbaldini@akingump.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
06/16/2023	1	COMPLAINT against XAVIER BECERRA IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (Filing and Admin fee $ 402 receipt number ANJDC-14396672), filed by BRISTOL MYERS SQUIBB COMPANY. (Attachments: # 1 Civil Cover Sheet, # 2 Certification Rule 11.2 Certification)(DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	2	Request for Summons to be Issued by BRISTOL MYERS SQUIBB COMPANY as to XAVIER BECERRA IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	3	Request for Summons to be Issued by BRISTOL MYERS SQUIBB COMPANY as to CHIQUITA BROOKS-LASURE. (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	4	Request for Summons to be Issued by BRISTOL MYERS SQUIBB COMPANY as to U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES. (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	5	Request for Summons to be Issued by BRISTOL MYERS SQUIBB COMPANY as to CENTERS FOR MEDICARE & MEDICAID SERVICES. (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	6	Request for Summons to be Issued by BRISTOL MYERS SQUIBB COMPANY as to XAVIER BECERRA IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES. (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	7	Request for Summons to be Issued by BRISTOL MYERS SQUIBB COMPANY as to XAVIER BECERRA IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES. (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	8	NOTICE of Appearance by JENNIFER LYNN DEL MEDICO on behalf of BRISTOL MYERS SQUIBB COMPANY (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)
06/16/2023	9	Corporate Disclosure Statement by BRISTOL MYERS SQUIBB COMPANY identifying None as Corporate Parent.. (DEL MEDICO, JENNIFER) (Entered: 06/16/2023)

06/20/2023		Judge Robert Kirsch and Magistrate Judge J. Brendan Day added. (jdg) (Entered: 06/20/2023)
06/20/2023	10	SUMMONS ISSUED as to XAVIER BECERRA, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES. Attached is the official court Summons, please fill out Defendant and Plaintiffs attorney information and serve. (jdg) (Entered: 06/20/2023)
07/07/2023	11	NOTICE of Appearance by JEFFREY J. GREENBAUM on behalf of BRISTOL MYERS SQUIBB COMPANY (GREENBAUM, JEFFREY) (Entered: 07/07/2023)
07/07/2023	12	NOTICE of Appearance by KATHERINE MARGUERITE LIEB on behalf of BRISTOL MYERS SQUIBB COMPANY (LIEB, KATHERINE) (Entered: 07/07/2023)
07/12/2023	13	STIPULATION *and PROPOSED ORDER re: IRA Briefing Schedule* by BRISTOL MYERS SQUIBB COMPANY. (GREENBAUM, JEFFREY) (Entered: 07/12/2023)
07/12/2023	14	AFFIDAVIT of Service for Summons and Complaint served on Xavier Becerra, U.S. Secretary of Health & Human Services on 06/21/2023 via Certified Mail, Return Receipt Requested., filed by BRISTOL MYERS SQUIBB COMPANY. (LIEB, KATHERINE) (Entered: 07/12/2023)
07/12/2023	15	AFFIDAVIT of Service for Summons and Complaint served on Chiquita Brooks-LaSure, Administrator of Centers for Medicare & Medicaid Services on 06/21/2023 via Certified Mail, Return Receipt Requested, filed by BRISTOL MYERS SQUIBB COMPANY. (LIEB, KATHERINE) (Entered: 07/12/2023)
07/12/2023	16	AFFIDAVIT of Service for Summons and Complaint served on Centers For Medicare & Medicaid Services on 06/21/2023 via Certified Mail, Return Receipt Requested, filed by BRISTOL MYERS SQUIBB COMPANY. (LIEB, KATHERINE) (Entered: 07/12/2023)
07/12/2023	17	AFFIDAVIT of Service for Summons and Complaint served on United States Department Health & Human Services on 06/21/2023, via Certified Mail, Return Receipt Requested., filed by BRISTOL MYERS SQUIBB COMPANY. (LIEB, KATHERINE) (Entered: 07/12/2023)
07/12/2023	18	AFFIDAVIT of Service for Summons and Complaint served on Merrick B. Garland, United States Attorney General on 06/21/2023, via Certified Mail, Return Receipt Requested., filed by BRISTOL MYERS SQUIBB COMPANY. (LIEB, KATHERINE) (Entered: 07/12/2023)
07/12/2023	19	AFFIDAVIT of Service for Summons and Complaint served on Civil Process Clerk, U.S. Attorney's Office, District of New Jersey on 06/21/2023, via Certified Mail, Return Receipt Requested., filed by BRISTOL MYERS SQUIBB COMPANY. (LIEB, KATHERINE) (Entered: 07/12/2023)
07/12/2023	20	NOTICE of Appearance by STEPHEN MICHAEL PEZZI on behalf of All Defendants (PEZZI, STEPHEN) (Entered: 07/12/2023)
07/12/2023	21	NOTICE by All Defendants *of Designation of Agent for Service Under Local Civil Rule 101.1(f)* (PEZZI, STEPHEN) (Entered: 07/12/2023)
07/14/2023	22	MOTION for Leave to Appear Pro Hac Vice by BRISTOL MYERS SQUIBB COMPANY. (Attachments: # 1 Declaration of Jeffrey J. Greenbaum, # 2 Declaration of Toni-Ann Citera, # 3 Declaration of Rajeev Muttreja, # 4 Declaration of Noel J. Francisco, # 5 Declaration of Jacob M. Roth, # 6 Declaration of Brett A. Shumate, # 7 Declaration of Charles E.T. Roberts, # 8 Text of Proposed Order, # 9 Certificate of Service)(GREENBAUM, JEFFREY) (Entered: 07/14/2023)

07/17/2023		Set Deadlines as to 22 MOTION for Leave to Appear Pro Hac Vice . Motion set for 8/7/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (mlh) (Entered: 07/17/2023)
07/20/2023	23	NOTICE of Appearance by ALEXANDER V SVERDLOV on behalf of All Defendants (SVERDLOV, ALEXANDER) (Entered: 07/20/2023)
07/20/2023	24	NOTICE of Appearance by CHRISTINE L. COOGLE on behalf of All Defendants (COOGLE, CHRISTINE) (Entered: 07/20/2023)
07/21/2023	25	TEXT ORDER REASSIGNING CASE. Case reassigned to Judge Zahid N. Quraishi for all further proceedings. Judge Robert Kirsch no longer assigned to case. So Ordered by Chief Judge Renee Marie Bumb on 7/21/2023. (jjc,) (Entered: 07/21/2023)
07/21/2023	26	Letter from Jeffrey J. Greenbaum to Judge Quraishi regarding case schedule and service of summary judgment motion. (GREENBAUM, JEFFREY) (Entered: 07/21/2023)
07/26/2023	27	ORDER granting 22 Motion for Leave to Appear Pro Hac Vice as to Toni-Ann Citera, Rajeev Muttreja, Noel J. Francisco, Jacob M. Roth, Brett A. Shumate, and Charles E.T. Roberts. Signed by Magistrate Judge J. Brendan Day on 7/26/2023. (jdg) (Entered: 07/26/2023)
07/28/2023	28	Notice of Request by Pro Hac Vice Toni-Ann Citera to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14489285.) (GREENBAUM, JEFFREY) (Entered: 07/28/2023)
07/28/2023	29	Notice of Request by Pro Hac Vice Noel J. Francisco to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14489348.) (GREENBAUM, JEFFREY) (Entered: 07/28/2023)
07/28/2023	30	Notice of Request by Pro Hac Vice Rajeev Muttreja to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14489403.) (GREENBAUM, JEFFREY) (Entered: 07/28/2023)
07/28/2023	31	Notice of Request by Pro Hac Vice Charles E.T. Roberts to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14489434.) (GREENBAUM, JEFFREY) (Entered: 07/28/2023)
07/28/2023	32	Notice of Request by Pro Hac Vice Jacob (Yaakov) M. Roth to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14489475.) (GREENBAUM, JEFFREY) (Entered: 07/28/2023)
07/28/2023	33	Notice of Request by Pro Hac Vice Brett A. Shumate to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14489485.) (GREENBAUM, JEFFREY) (Entered: 07/28/2023)
07/28/2023	34	Letter from Defendants in response to Plaintiff's letter of July 21 and regarding the parties' joint proposed schedule re 26 Letter. (Attachments: # 1 Text of Proposed Order) (PEZZI, STEPHEN) (Entered: 07/28/2023)
07/31/2023		Pro Hac Vice counsel, TONI-ANN CITERA, NOEL J. FRANCISCO, RAJEEV MUTTREJA, CHARLES E.T. ROBERTS, JACOB M. ROTH and BRETT A. SHUMATE, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (mlh) (Entered: 07/31/2023)

07/31/2023	35	ORDER that the herein schedule shall govern further proceedings in this case. It is ORDERED that the parties need not file statements of material fact under Local Civil Rule 56.1(a) and it is further ORDERED that Defendants need not file an answer to the Complaints. Signed by Judge Zahid N. Quraishi on 7/31/2023. (mlh) (Entered: 07/31/2023)
08/16/2023	36	MOTION for Summary Judgment by BRISTOL MYERS SQUIBB COMPANY. (Attachments: # 1 Declaration of Christopher T. Mancill, # 2 Declaration of Toni-Ann Citera, # 3 Brief Memorandum of Law, # 4 Text of Proposed Order Proposed form of Order, # 5 Certificate of Service)(GREENBAUM, JEFFREY) (Entered: 08/16/2023)
08/17/2023		Set Deadlines as to 36 MOTION for Summary Judgment . Motion set for 9/18/2023 before Judge Zahid N. Quraishi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (mlh) (Entered: 08/17/2023)
08/29/2023	37	MOTION for Leave to Appear Amicus Curiae by FRESENIUS KABI USA, LLC. (Attachments: # 1 Brief)(QUINN, JUSTIN) (Entered: 08/29/2023)
08/30/2023		Set Deadlines as to 37 MOTION for Leave to Appear Amicus Curiae . Motion set for 10/2/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (mlh) (Entered: 08/30/2023)
10/16/2023	38	Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion* by All Defendants. Responses due by 11/10/2023. (Attachments: # 1 Brief, # 2 Text of Proposed Order)(SVERDLOV, ALEXANDER) (Entered: 10/16/2023)
10/17/2023		Set Deadlines as to 38 Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion*. Motion set for 11/20/2023 before Judge Zahid N. Quraishi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (kht) (Entered: 10/17/2023)
10/17/2023	39	MOTION for Leave to File *Brief of Amici Curiae Public Citizen, et al.*, MOTION for Leave to Appear Amicus Curiae *Brief* by Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA. (Attachments: # 1 Brief) (MILZ, ANDREW) (Entered: 10/17/2023)
10/17/2023	40	Corporate Disclosure Statement by Doctors for America, Families USA, Patients for Affordable Drugs Now, Protect Our Care, Public Citizen. (MILZ, ANDREW) (Entered: 10/17/2023)
10/17/2023	41	Amicus Curiae APPEARANCE entered by GLEN D. SAVITS on behalf of AARP, AARP Foundation. (SAVITS, GLEN) (Entered: 10/17/2023)
10/18/2023		Set Deadlines as to 39 MOTION for Leave to File *Brief of Amici Curiae Public Citizen, et al.* MOTION for Leave to Appear Amicus Curiae *Brief*. Motion set for 11/20/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (kht) (Entered: 10/18/2023)
10/18/2023		CLERK'S QUALITY CONTROL MESSAGE - A Text of Proposed Order was not submitted with the 39 Motion for leave to file submitted by Andrew Milz on 10/17/2023.

		PLEASE SUBMIT THE MISSING DOCUMENT ONLY USING EVENT *Exhibit to Document* and linking it to the Motion. (kht) (Entered: 10/18/2023)
10/18/2023	42	Exhibit to 39 Motion for Leave to File,, Appear Amicus Curiae, by Doctors for America, Families USA, Patients for Affordable Drugs Now, Protect Our Care, Public Citizen. (MILZ, ANDREW) (Entered: 10/18/2023)
10/18/2023	43	MOTION for Leave to Appear Pro Hac Vice *Granting the Pro Hac Vice Admission of Allison Horwitz* by AARP, AARP Foundation. (Attachments: # 1 Declaration of Glen D. Savits, # 2 Declaration of Allison Horwitz, # 3 Text of Proposed Order, # 4 Certificate of Service)(SAVITS, GLEN) (Entered: 10/18/2023)
10/19/2023		Set Deadlines as to 43 MOTION for Leave to Appear Pro Hac Vice *Granting the Pro Hac Vice Admission of Allison Horwitz*. Motion set for 11/20/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg,) (Entered: 10/19/2023)
10/19/2023	44	MOTION for Leave to Appear Pro Hac Vice by Intellectual Property Law and Health Law Scholars. (Attachments: # 1 Declaration of James E. Cecchi, # 2 Declaration of Hannah W. Brennan, # 3 Declaration of Claudia Morera, # 4 Declaration of Rebekah GlickmanSimon, # 5 Text of Proposed Order)(CECCHI, JAMES) (Entered: 10/19/2023)
10/20/2023	45	ORDER granting 43 Motion for Leave to Appear Pro Hac Vice as to Allison Horwitz. Signed by Magistrate Judge J. Brendan Day on 10/20/2023. (jal,) (Entered: 10/20/2023)
10/20/2023		Set Deadlines as to 44 MOTION for Leave to Appear Pro Hac Vice . Motion set for 11/20/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg) (Entered: 10/20/2023)
10/23/2023	46	MOTION for Leave to Appear Amicus Curiae by AARP, AARP Foundation. (Attachments: # 1 Brief, # 2 Text of Proposed Order)(SAVITS, GLEN) (Entered: 10/23/2023)
10/23/2023	47	MOTION for Leave to Appear Amicus Curiae by American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology. (Attachments: # 1 Brief Proposed Amicus Brief, # 2 Proposed Order)(GITOMER, MADELINE) (Entered: 10/23/2023)
10/23/2023	48	Corporate Disclosure Statement by American College of Physicians, American Geriatrics Society, American Public Health Association, American Society of Hematology, Society of General Internal Medicine. (GITOMER, MADELINE) (Entered: 10/23/2023)
10/23/2023	49	Consent MOTION for Leave to Appear Pro Hac Vice by American College of Physicians, American Geriatrics Society, American Public Health Association, American Society of Hematology, Society of General Internal Medicine. (Attachments: # 1 Declaration Sponsoring Attorney, # 2 Declaration Burra, # 3 Declaration Seel, # 4 Declaration Thurston, # 5 Proposed Order)(GITOMER, MADELINE) (Entered: 10/23/2023)
10/23/2023	50	ORDER granting 44 Motion for Leave to Appear Pro Hac Vice as to, HANNAH W. BRENNAN, CLAUDIA MORERA, and REBEKAH GLICKMAN-SIMON,. Signed by Magistrate Judge J. Brendan Day on 10/23/2023. (jdg) (Entered: 10/23/2023)
10/23/2023	51	MOTION for Leave to Appear Amicus Curiae by Nationally Recognized Healthcare and Medicare Experts. (Attachments: # 1 Brief in Support of Motion to File a Brief as Amici Curiae in Support of Defendants' Cross Motion for Summary Judgment and in Opposition

		to Plaintiffs' Motions for Summary Judgment, # 2 Text of Proposed Order)(LEARDI, JOHN) (Entered: 10/23/2023)
10/23/2023	52	Consent MOTION for Leave to Appear Pro Hac Vice by Nationally Recognized Healthcare and Medicare Experts. (Attachments: # 1 Certification of John W. Leardi, # 2 Certification of William B. Schultz, # 3 Certification of Margaret M. Dotzel, # 4 Certification of Alyssa M. Howard, # 5 Text of Proposed Order, # 6 Certificate of Service)(LEARDI, JOHN) (Entered: 10/23/2023)
10/23/2023	53	MOTION for Leave to File *Amicus Curiae Brief in Support of Defendants* by Constitutional Accountability Center. (Attachments: # 1 Proposed Brief of Amicus Curiae, # 2 Corporate Disclosure Statement, # 3 Text of Proposed Order)(LEATHERS, DANIEL) (Entered: 10/23/2023)
10/23/2023	54	MOTION for Leave to Appear Amicus Curiae by LAW SCHOLARS. (Attachments: # 1 Brief, # 2 Text of Proposed Order, # 3 Proposed Brief of Amici Curiae Law Scholars) (ECKLUND, DONALD) (Entered: 10/23/2023)
10/23/2023	55	NOTICE of Appearance by ALEC BERIN on behalf of Economists and Scholars of Health Policy as Amici Curiae (BERIN, ALEC) (Entered: 10/23/2023)
10/23/2023	56	NOTICE of Appearance by JAMES C. SHAH on behalf of Economists and Scholars of Health Policy as Amici Curiae (SHAH, JAMES) (Entered: 10/23/2023)
10/23/2023	57	MOTION for Leave to File by Economists and Scholars of Health Policy as Amici Curiae. (Attachments: # 1 Brief of Economists and Scholars of Health Policy as Amici Curiae in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment)(SHAH, JAMES) (Entered: 10/23/2023)
10/24/2023		Set Deadlines as to 51 MOTION for Leave to Appear Amicus Curiae , 49 Consent MOTION for Leave to Appear Pro Hac Vice , 54 MOTION for Leave to Appear Amicus Curiae , 52 Consent MOTION for Leave to Appear Pro Hac Vice , 47 MOTION for Leave to Appear Amicus Curiae , 46 MOTION for Leave to Appear Amicus Curiae , 57 MOTION for Leave to File , 53 MOTION for Leave to File *Amicus Curiae Brief in Support of Defendants*. Motion set for 11/6/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (kht) (Entered: 10/24/2023)
10/24/2023	58	MOTION for Leave to Appear Pro Hac Vice *as to Elizabeth Wydra, Brianne Gorod, and Nina Henry* by Constitutional Accountability Center. (Attachments: # 1 Certification of Daniel R. Leathers, # 2 Certification of Elizabeth Wydra, # 3 Certification of Brianne Gorod, # 4 Certification of Nina Henry, # 5 Text of Proposed Order)(LEATHERS, DANIEL) (Entered: 10/24/2023)
10/25/2023	59	ORDER granting 49 Motion for Leave to Appear Pro Hac Vice as to AMANDA V. BURRA, ESQ., BENJAMIN SEEL, ESQ., and ROBIN F. THURSTON, ESQ. Signed by Magistrate Judge J. Brendan Day on 10/25/2023. (mlh) (Entered: 10/25/2023)
10/25/2023	60	ORDER granting 52 Motion for Leave to Appear Pro Hac Vice as to WILLIAM B. SCHULTZ, ESQ., MARGARET M. DOTZEL, ESQ., and ALYSSA M. HOWARD, ESQ. Signed by Magistrate Judge J. Brendan Day on 10/25/2023. (mlh) (Entered: 10/25/2023)
10/25/2023		Set Deadlines as to 58 MOTION for Leave to Appear Pro Hac Vice *as to Elizabeth Wydra, Brianne Gorod, and Nina Henry*. Motion set for 11/20/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically

		generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jal,) (Entered: 10/25/2023)
10/27/2023	61	ORDER granting 58 Motion for Leave to Appear Pro Hac Vice as to Elizabeth Wydra, Brianne Gorod and Nina Henry. Signed by Magistrate Judge J. Brendan Day on 10/27/2023. (kht) (Entered: 10/27/2023)
10/30/2023	62	MOTION for Leave to Appear Pro Hac Vice *of Wendy Liu* by Doctors for America, Families USA, Patients for Affordable Drugs Now, Protect Our Care, Public Citizen. (Attachments: # 1 Certification of Andrew M. Milz, # 2 Text of Proposed Order)(MILZ, ANDREW) (Entered: 10/30/2023)
10/30/2023	63	MOTION for Leave to Appear Pro Hac Vice *of Wendy Liu* by Doctors for America, Families USA, Patients for Affordable Drugs Now, Protect Our Care, Public Citizen. (Attachments: # 1 Certification of Andrew M. Milz, # 2 Text of Proposed Order)(MILZ, ANDREW) (Entered: 10/30/2023)
10/30/2023	64	MOTION for Leave to Appear Amicus Curiae by Abrams Institute for Freedom of Expression. (Attachments: # 1 Text of Proposed Order, # 2 Brief in support of motion for leave to file amicus brief, # 3 Brief Exh. A (MERITS AMICUS BRIEF))(KOMUVES, FLAVIO) (Entered: 10/30/2023)
10/31/2023		Set Deadlines as to 62 MOTION for Leave to Appear Pro Hac Vice *of Wendy Liu*. Motion set for 12/4/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (amv) (Entered: 10/31/2023)
10/31/2023		CLERK'S QUALITY CONTROL MESSAGE - The Motion for Leave to Appear Pro Hac 63 filed by ANDREW MILZ on 10/30/23 appears to be filed in the incorrect case. PLEASE REVIEW THE MOTION and file it in the correct case. The Clerk's Office has terminated the Motion. This submission will remain on the docket unless otherwise ordered by the court. (amv) (Entered: 10/31/2023)
10/31/2023	65	Notice of Request by Pro Hac Vice Benjamin Seel to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14835270.) (GITOMER, MADELINE) (Entered: 10/31/2023)
10/31/2023	66	Notice of Request by Pro Hac Vice Ananda V. Burra to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14835312.) (GITOMER, MADELINE) (Entered: 10/31/2023)
10/31/2023	67	Notice of Request by Pro Hac Vice Robin F. Thurston to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14835327.) (GITOMER, MADELINE) (Entered: 10/31/2023)
10/31/2023	68	Notice of Request by Pro Hac Vice Elizabeth Wydra to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14836406.) (LEATHERS, DANIEL) (Entered: 10/31/2023)
10/31/2023	69	Notice of Request by Pro Hac Vice Brianne Gorod to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14836423.) (LEATHERS, DANIEL) (Entered: 10/31/2023)
10/31/2023	70	Notice of Request by Pro Hac Vice Nina Henry to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14836431.) (LEATHERS, DANIEL) (Entered: 10/31/2023)

11/01/2023		Pro Hac Vice counsel, BENJAMIN SEEL, ANANDA V. BURRA and ROBIN F. THURSTON, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (kht) (Entered: 11/01/2023)
11/01/2023		Pro Hac Vice counsel, ELIZABETH WYDRA, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (mlh) (Entered: 11/01/2023)
11/01/2023		Pro Hac Vice counsel, BRIANNE GOROD, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (mlh) (Entered: 11/01/2023)
11/01/2023		Pro Hac Vice counsel, NINA HENRY, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (mlh) (Entered: 11/01/2023)
11/01/2023	71	MOTION for Leave to Appear Pro Hac Vice *of David A. Schulz* by Abrams Institute for Freedom of Expression. (Attachments: # 1 Declaration of David A. Schulz, # 2 Declaration of Flavio L. Komuves, # 3 Text of Proposed Order Proposed Order) (KOMUVES, FLAVIO) (Entered: 11/01/2023)
11/01/2023	72	Notice of Request by Pro Hac Vice Allison Horwitz to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14839463.) (SAVITS, GLEN) (Entered: 11/01/2023)
11/02/2023	73	Letter from Defendants on behalf of all parties requesting a 14-day extension of all remaining briefing deadlines. (Attachments: # 1 Text of Proposed Order)(PEZZI, STEPHEN) (Entered: 11/02/2023)
11/02/2023		Set Deadlines as to 71 MOTION for Leave to Appear Pro Hac Vice *of David A. Schulz*. Motion set for 12/4/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (kht) (Entered: 11/02/2023)
11/02/2023		Pro Hac Vice counsel, ALLISON HORWITZ, ESQ., has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (amv) (Entered: 11/02/2023)
11/03/2023	74	CONSENT ORDER that Plaintiffs' combined replies in support of their motions for summary judgment and oppositions to Defendants' cross-motion for summary judgment shall be due 11/24/2023 and Defendants' reply in support of their cross-motion for summary judgment shall be due 12/22/2023. Signed by Judge Zahid N. Quraishi on 11/3/2023. (mlh) (Entered: 11/03/2023)
11/03/2023	75	Notice of Request by Pro Hac Vice William B. Schultz to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14846472.) (LEARDI, JOHN) (Entered: 11/03/2023)
11/03/2023	76	Notice of Request by Pro Hac Vice Margaret M. Dotzel to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14846511.) (LEARDI, JOHN) (Entered: 11/03/2023)

11/03/2023	77	Notice of Request by Pro Hac Vice Alyssa M. Howard to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14846534.) (LEARDI, JOHN) (Entered: 11/03/2023)
11/06/2023		Pro Hac Vice counsel, WILLIAM B. SCHULTZ, MARGARET M. DOTZEL and ALYSSA M. HOWARD, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (jal,) (Entered: 11/06/2023)
11/06/2023		Set/Reset Deadlines as to 64 MOTION for Leave to Appear Amicus Curiae . Motion set for 12/4/2023 before Judge Zahid N. Quraishi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jjc,) (Entered: 11/06/2023)
11/21/2023	78	ORDER granting 71 Motion for Leave to Appear Pro Hac Vice, as to DAVID A. SCHULZ. Signed by Magistrate Judge J. Brendan Day on 11/21/2023. (jdg) (Entered: 11/21/2023)
11/21/2023	79	ORDER granting 62 Motion for Leave to Appear Pro Hac Vice as to, WENDY LIU. Signed by Magistrate Judge J. Brendan Day on 11/21/2023. (jdg) (Entered: 11/21/2023)
11/24/2023	80	RESPONSE to Motion filed by BRISTOL MYERS SQUIBB COMPANY re 36 MOTION for Summary Judgment , 38 Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion (Plaintiff's Combined Opposition to Defendants' Motion for Summary Judgment and Reply in Support of Plaintiff's Motion for Summary Judgment)* (Attachments: # 1 Certificate of Service)(GREENBAUM, JEFFREY) (Entered: 11/24/2023)
11/28/2023		Pro Hac Vice fee for WINDY LIU: $ 300, receipt number NEW49310 ($150 for 23-3335, $150 for 23-3818) (jr) (Entered: 11/28/2023)
11/28/2023		Pro Hac Vice fee received for David A. Schulz: $ 150, receipt number 135816 (jjc,) (Entered: 11/28/2023)
11/29/2023	81	Notice of Request by Pro Hac Vice David A. Schulz to receive Notices of Electronic Filings. (KOMUVES, FLAVIO) (Entered: 11/29/2023)
11/30/2023		Pro Hac Vice counsel, DAVID A. SCHULZ, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (mlh) (Entered: 11/30/2023)
12/06/2023	82	Letter from Defendants regarding consent request for extension of page limit. (Attachments: # 1 Text of Proposed Order)(COOGLE, CHRISTINE) (Entered: 12/06/2023)
12/07/2023	83	CONSENT ORDER that Defendants shall file a combined reply brief not to exceed 45 pages. Signed by Judge Zahid N. Quraishi on 12/7/2023. (kht) (Entered: 12/07/2023)
12/22/2023	84	REPLY to Response to Motion filed by All Defendants re 38 Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion* (SVERDLOV, ALEXANDER) (Entered: 12/22/2023)
01/11/2024	85	ORDER that The Abrams Institute for Freedom of Expression's 64 Motion for leave to appear and file a brief as amicus curiae is hereby GRANTED. The Abrams Institute shall

		file its proposed amicus curiae brief within 5 days. Signed by Judge Zahid N. Quraishi on 1/11/2024. (kht) (Entered: 01/11/2024)
01/12/2024	86	TEXT ORDER granting Motions to Appear Amicus Curiae 37 , 39 , 46 , 47 , 51 , 53 , 54 , and 57 . Proposed Amicus briefs to be filed within 5 days. So Ordered by Judge Zahid N. Quraishi on 1/12/2024. (Gonzalez, P) (Entered: 01/12/2024)
01/12/2024	87	BRIEF *OF AMICI CURIAE PUBLIC CITIZEN, PATIENTS FOR AFFORDABLE DRUGS NOW, DOCTORS FOR AMERICA, PROTECT OUR CARE, AND FAMILIES USA IN SUPPORT OF DEFENDANTS OPPOSITION TO PLAINTIFFS MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION* (MILZ, ANDREW) (Entered: 01/12/2024)
01/12/2024	88	BRIEF *of Amicus Curiae Abrams Institute for Freedom of Expression in Support of Defendants' Opposition to Plaintiff's Motion for Summary Judgment and Cross-Motion* (KOMUVES, FLAVIO) (Entered: 01/12/2024)
01/12/2024	89	BRIEF *OF AMICI CURIAE AARP AND AARP FOUNDATION SUPPORTING DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION* (SAVITS, GLEN) (Entered: 01/12/2024)
01/12/2024	90	BRIEF *OF ECONOMISTS AND SCHOLARS OF HEALTH POLICY AS AMICI CURIAE IN SUPPORT OF DEFENDANTS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS MOTION FOR SUMMARY JUDGMENT* (SHAH, JAMES) (Entered: 01/12/2024)
01/16/2024	91	BRIEF *of Amici Curiae American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, and American Society of Hematology* (GITOMER, MADELINE) (Entered: 01/16/2024)
01/17/2024	92	BRIEF *OF NATIONALLY RECOGNIZED HEALTHCARE AND MEDICARE EXPERTS AS AMICI CURIAE IN SUPPORT OF DEFENDANTS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS MOTIONS FOR SUMMARY JUDGMENT* (LEARDI, JOHN) (Entered: 01/17/2024)
01/17/2024	93	BRIEF *of Constitutional Accountability Center as Amicus Curiae in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment* (LEATHERS, DANIEL) (Entered: 01/17/2024)
01/19/2024	94	BRIEF *of Amici Curiae American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, and American Society of Hematology* (GITOMER, MADELINE) (Entered: 01/19/2024)
01/19/2024	95	Letter from Amici Curiae American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, and American Society of Hematology re 91 Brief, 94 Brief. (GITOMER, MADELINE) (Entered: 01/19/2024)
02/07/2024	96	TEXT ORDER that the Court will conduct oral argument for the pending Motions for Summary Judgment in related cases 23-cv-3335, 23-cv-3818, 23-cv-14221, 23- cv-20814. Argument will be heard from the parties only. The Court has availability from 03/05/2024 through 03/08/2024 from 10:00 a.m. through 2:00 p.m. By 02/16/2024, counsel are to meet and confer and file a letter proposing: (1) dates for argument; and (2) a schedule for argument. So Ordered by Judge Zahid N. Quraishi on 2/7/2024. (kas) (Entered: 02/07/2024)
02/20/2024	97	TEXT ORDER that the Court has reviewed the parties' letter regarding oral argument that was filed in 23-cv-3818 Janssen v. Becerra at ECF No. 87 . The Court adopts Plaintiffs' position. Oral argument for the four related matters (23-cv-3335, 23-cv-3818, 23-14221,

		and 23-20814) will be heard on 03/07/2024 beginning at 10:00 a.m., tentatively scheduled to conclude by 2:30 p.m. As previously noted, only the parties will be arguing. So Ordered by Judge Zahid N. Quraishi on 2/20/2024. (kas) (Entered: 02/20/2024)
02/29/2024	98	NOTICE of Appearance by HEATHER CARNEY COSTANZO on behalf of All Defendants (COSTANZO, HEATHER) (Entered: 02/29/2024)
03/04/2024	99	NOTICE of Appearance by CASSANDRA SNYDER on behalf of All Defendants (SNYDER, CASSANDRA) (Entered: 03/04/2024)
03/04/2024	100	NOTICE by All Defendants *of Supplemental Persuasive Authority* (Attachments: # 1 Exhibit A - AstraZeneca Opinion)(SNYDER, CASSANDRA) (Entered: 03/04/2024)
03/04/2024	101	NOTICE of Appearance by BRIAN DAVID NETTER on behalf of All Defendants (NETTER, BRIAN) (Entered: 03/04/2024)
03/05/2024	102	Letter from Jeffrey J. Greenbaum, Esq. regarding responding to Government request to consider supplemental authority re 100 Notice (Other), 80 Response to Motion,. (GREENBAUM, JEFFREY) (Entered: 03/05/2024)
03/05/2024	103	MOTION for Leave to Appear Amicus Curiae by Alliance for Aging Research. (Attachments: # 1 Memorandum in Support, # 2 Proposed Amicus Brief, # 3 Text of Proposed Order)(BALDINI, STEPHEN) (Entered: 03/05/2024)
03/06/2024	104	TEXT ORDER granting 103 Motion to Appear Amicus Curiae. Amicus Curiae shall file their proposed briefs within 7 days. So Ordered by Judge Zahid N. Quraishi on 3/6/2024. (kas) (Entered: 03/06/2024)
03/07/2024	105	BRIEF *of Amicus Curiae Alliance for Aging Research* (BALDINI, STEPHEN) (Entered: 03/07/2024)
03/07/2024	106	Minute Entry for proceedings held before Judge Zahid N. Quraishi: Oral Argument on Motion for Summary Judgment 30 and Cross-Motion for Summary Judgment 33 in 23-3818 heard with related cases, 23-20814 MSJ 28 and Cross- MSJ 37 , 23-3335 MSJ 36 and Cross-MSJ 38 and 23-14221 MSJ 18 and Cross- MSJ 24 held on 3/7/2024. Court Reserves Decision. (Court Reporter, Megan McKay-Soule (609-815-2319) (kas,) (Entered: 03/07/2024)
03/14/2024	107	Transcript of Oral Argument held on 3/7/2024, before Judge Judge ZAHID N. QURAISHI. Court Reporter/Transcriber Megan McKay-Soule (609-815-2319). **NOTICE REGARDING (1) REDACTION OF PERSONAL IDENTIFIERS IN TRANSCRIPTS AND (2) MOTION TO REDACT AND SEAL:** The parties have seven (7) calendar days to file with the Court a Notice of Intent to Request Redaction of this Transcript to comply with Fed.R.Civ.P.5.2(a) (personal identifiers). Parties seeking to redact and seal this Transcript, or portions thereof, pursuant to L.Civ.R. 5.3(g) must e-file a Motion to Redact and Seal utilizing the event `Redact and Seal Transcript/Digital Recording`. Redaction Request to Court Reporter/Transcription Agency due, but not filed, by 4/4/2024. Redacted Transcript Deadline set for 4/15/2024. Release of Transcript Restriction set for 6/12/2024. (jal,) (Entered: 03/14/2024)
04/15/2024	108	Letter from Jeffrey J. Greenbaum to Judge Quraishi regarding notice of supplemental authority.. (Attachments: # 1 Exhibit A - Sheetz v. County of El Dorado)(GREENBAUM, JEFFREY) (Entered: 04/15/2024)
04/18/2024	109	Letter from counsel for Defendants re 108 Letter. (SVERDLOV, ALEXANDER) (Entered: 04/18/2024)
04/29/2024	110	OPINION filed. Signed by Judge Zahid N. Quraishi on 4/29/2024. (jdg) (Entered: 04/29/2024)

04/29/2024	111	ORDER that Defendants' 33 Motion for Summary Judgment is GRANTED. Plaintiff's 30 Motion for Summary Judgment is DENIED. The Clerk is directed to mark this matter as CLOSED. Signed by Judge Zahid N. Quraishi on 4/29/2024. (jdg) (Entered: 04/29/2024)
04/29/2024	112	APPEAL OF MAGISTRATE JUDGE DECISION to District Court by BRISTOL MYERS SQUIBB COMPANY re 110 Opinion, 111 Order (Attachments: # 1 Certificate of Service)(GREENBAUM, JEFFREY) (Entered: 04/29/2024)
04/29/2024	113	NOTICE OF APPEAL as to 111 Order, 110 Opinion by BRISTOL MYERS SQUIBB COMPANY. Filing fee $ 605, receipt number ANJDC-15326762. The Clerk's Office hereby certifies the record and the docket sheet available through ECF to be the certified list in lieu of the record and/or the certified copy of the docket entries. Appeal Record due by 4/29/2024. (Attachments: # 1 Certificate of Service)(GREENBAUM, JEFFREY) (Entered: 04/29/2024)
04/29/2024		***Civil Case Terminated per 111 . (eaj) (Entered: 04/30/2024)
04/30/2024		CLERKS QUALITY CONTROL MESSAGE - The Notice of Appeal, 112 filed by BRISTOL MYERS SQUIBB COMPANY on 4/29/2024, was submitted incorrectly as an *Appeal of a Magistrate Judge Decision to the District Court* and subsequently refiled USING THE CORRECT EVENT *Notice of Appeal (USCA Philadelphia)*. The calendar event created by the original filing has been terminated. This message is for informational purposes only. This submission will remain on the docket unless otherwise ordered by the court. (eaj,) (Entered: 04/30/2024)
05/06/2024	114	USCA Case Number 24-1820 for 113 Notice of Appeal (USCA), filed by BRISTOL MYERS SQUIBB COMPANY. USCA Case Manager Stephanie (Document Restricted - Court Only) (ca3sb,) (Entered: 05/06/2024)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff,

v.

XAVIER BECERRA, U.S. Secretary of Health & Human Services; CHIQUITA BROOKS-LASURE, Administrator of Centers for Medicare & Medicaid Services; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

Civil Action No. _____

COMPLAINT

INTRODUCTION

1. When Congress enacted the Medicare "Drug Price Negotiation Program" (the Program) in the Inflation Reduction Act (IRA) last summer, it did so under the guise of merely empowering Medicare to "negotiate" directly with pharmaceutical companies to enter voluntary price "agreements" for certain medications. In truth, however, Congress did something entirely different. Contrary to its name, the Program does not involve "negotiations" in any ordinary sense of the word. Nor does it result in real "agreements" between Medicare and pharmaceutical companies.

2. Rather, the Program creates an unprecedented regime whereby the Secretary of the U.S. Department of Health and Human Services (HHS) dictates a price at which pharmaceutical companies are compelled to sell their most innovative and

successful medicines or else face unconscionable penalties. Moreover, Congress sought to mask the reality of this Government-controlled scheme by forcing the companies to participate in a faux "negotiation" process and then express their "agreement" that whatever price HHS chooses is "the maximum fair price" for their medicines.

3. The Program works like this: HHS unilaterally selects a series of pharmaceuticals for inclusion. The manufacturer of each chosen pharmaceutical is then compelled to enter an "agreement" with HHS committing to provide the medicine to Medicare beneficiaries at whatever price the agency determines (in its purportedly unreviewable discretion) to be "fair." That price is capped at a fixed fraction of a benchmark market price for the pharmaceutical (and HHS is free to set the price even lower). If the company does not sign such an "agreement" by the statutory deadline, or does not ultimately "agree" that the price dictated by HHS is a "fair" price in a public contract, it must pay a penalty (which the IRA deceptively calls a "tax") that is multiples of the pharmaceutical's overall revenues—day after day, until the company relents.

4. Unlike a true "negotiation," this Program guarantees that the Government will secure the products it wants at the prices it dictates—the exponentially higher penalty makes that certain. This "negotiation" is akin to the Government telling you how much it will pay to buy your house (capped at a fraction of the assessed market value), and then forcing you to sign an agreement turning over the house and announcing that the heavily discounted price is "fair," all under duress of having to pay a tax that dwarfs the home's true market value.

5. This Program is unconstitutional. Most obviously, the Fifth Amendment requires the Government to pay "just compensation" if it takes private "property" for public use. This fundamental protection prevents Medicare from outright seizing a portion of each pharmaceutical company's inventory. But compelling the transfer of the inventory at a unilaterally dictated *discount* is no different, either functionally or legally. The singular purpose of the Program is to allow Medicare to secure the pharmaceuticals without paying their fair value. It uses the threat of crippling penalties to accomplish that objective. That amounts to a classic, *per se* physical taking without the "just compensation" that the Constitution demands.

6. That is not the only constitutional infirmity in the way the IRA is structured. Rather than candidly admitting to the American people that it imposed mandatory price controls and forced sales, Congress filtered the IRA's requirements through a façade of "agreements" through which pharmaceutical manufacturers must convey that they "agree" to HHS's dictated prices and that they "agree" that such prices are the "the maximum fair price[s]" for their medicines. In other words, instead of simply *directing* the companies on what they *must* do, the IRA uses the threat of penalties to coerce the companies to *say they agree* to do it all *voluntarily*. That is unprecedented—and intentional. This structure serves the political purpose of masking unilateral price caps as voluntary "agreements" formed through genuine "negotiations," when they are not. But, under the First Amendment, the Government cannot conscript citizens (including businesses) to parrot its preferred political messaging.

7. The IRA violates the Constitution by forcing pharmaceutical companies to turn over their most successful and innovative products at a huge discount, while publicly pronouncing the transaction to be "fair." And these constitutional violations do not become permissible simply because the companies choose to accept federal reimbursements for selling their products to Medicare and Medicaid—together accounting for approximately half of all patients taking these medications.

8. For one thing, the IRA's mandates are enforced through monetary fines and penalties, not by imposing conditions on receipt of federal reimbursements. For another, manufacturers cannot "withdraw" from Medicare or Medicaid without giving notice up to *two years* in advance—which means that once a company's pharmaceutical is selected, it is too late to exit. For a third, Congress cannot leverage its Spending Clause power to coerce companies to forgo their rights. Hinging all Medicare and Medicaid participation on a faux "agreement" to sell a single medicine at an agency-dictated price is a quintessential example of an unconstitutional condition. It is constitutionally untenable to force companies to choose between abandoning their fundamental rights or cutting off tens of millions of patients from their medications.

9. In the end, the IRA's real victim is innovation—and, in turn, the millions of patients who are counting on the pharmaceutical industry to develop new therapies that save lives and improve health and wellbeing. Pharmaceutical manufacturers must take enormous financial risks to develop new medicines. The creation of such medicines requires billions of dollars of investment to fund extensive scientific research. And for

every success, many more ideas and experiments fail to produce a marketable medicine that secures approval from the Food and Drug Administration (FDA). Altogether, the realities of science allow only a tiny fraction of research projects to recoup their development costs. Because of that dynamic, manufacturers can afford to fund the research and development of future medicines only if the handful of products that succeed generate sufficient revenues to make those investments worthwhile. Yet the IRA targets precisely those most successful products, and dramatically undercuts their revenue stream. In doing so, the IRA will force pharmaceutical manufactuers to reduce their investments in potentially promising medicines and treatments. As a result, future life-saving treatments in areas such as cancer, Alzheimer's disease, and immunological and cardiovascular disease may never see the laboratory, much less achieve FDA approval, and will never reach the patients in need of such treatments.

10. This dystopian reality need not come to pass. This Court should declare that the Program effects compensable takings under the Fifth Amendment, and enjoin the Program's compelled "agreements" under the First Amendment.

PARTIES

11. Plaintiff Bristol Myers Squibb Company (BMS) is a U.S. pharmaceutical company with its principal place of business in Lawrenceville, New Jersey. BMS invests billions of dollars every year to research and develop medicines to address the unmet medical needs of patients with serious diseases, last year alone investing $9.5 billion in research and development and conducting over 460 clinical trials.

12. Among the life-saving medicines developed by BMS is Eliquis, which is used to prevent blood clots and strokes. Eliquis will be subject to the IRA's pricing scheme starting in 2023. Another BMS medicine, Opdivo—used to treat several types of cancer—will be chosen for a subsequent round of the Program. *See* S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation, 2026-2028*, 29 JMCP 229, 230–31 (Mar. 2023) (Dickson & Hernandez). And others will inevitably follow. BMS is the NDA (new drug application) holder for both Eliquis and Opdivo.

13. BMS is committed to providing access to its life-saving therapies. In 2022 alone, BMS donated approximately $3 billion in free medicine to independent charitable organizations to support over 155,000 patients in the United States. BMS also provided approximately $742 million to support organizations that help patients and their families, improve healthcare, advance scientific understanding, and foster strong communities.

14. Defendant Xavier Becerra is the Secretary of HHS. He oversees the Medicare program and is responsible for administering the statutory provisions challenged here. He is sued in his official capacity only.

15. Defendant Chiquita Brooks-LaSure is the Administrator of the Centers for Medicare & Medicaid Services (CMS). She administers the Program on behalf of the Secretary. She is sued in her official capacity only.

16. Defendant HHS is an executive department of the Federal Government headquartered in Washington, D.C. HHS is responsible for administering Medicare and the IRA provisions challenged here.

17. Defendant CMS is an administrative agency within HHS that administers Medicare, including the Program, on which it has already issued certain implementation guidance.

JURISDICTION AND VENUE

18. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States.

19. This Court may grant declaratory, injunctive, and other appropriate relief under 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 703–06. Equitable relief is also authorized under this Court's inherent powers.

20. Sovereign immunity poses no bar to this action for declaratory and injunctive relief. *See* 5 U.S.C. § 702.

21. There is an actual controversy between the parties. Based on Medicare Part D spending over the past 12 months, one of BMS's medicines, Eliquis, will be subject to the Program starting in September 2023. *See* Dickson & Hernandez, *supra*. Another BMS product, Opdivo, will be subject to the Program soon after. *See id.* And others will inevitably follow.

22. Venue is proper under 28 U.S.C. § 1391(e), because BMS's corporate headquarters is located within this District.

FACTUAL ALLEGATIONS

A. Background on the Medicare Program.

23. Through the Medicare program, the Federal Government operates one of the world's largest, and the most influential, health insurance programs. Medicare makes available to tens of millions of American beneficiaries the life-saving products developed by pharmaceutical companies like BMS.

24. Under Medicare Part B, manufacturers sell medications that physicians then administer, and the Government reimburses part of the costs.

25. Those eligible for Medicare Part B may also enroll in Medicare Part D, which allows beneficiaries to choose from various self-administered prescription pharmaceutical plans offered by private insurers that have contracted with the Government. Those contracts are awarded based on competitive bids, which specify the pharmaceutical costs the Government would reimburse upfront. R. Knox, *More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States*, 18 YALE J. HEALTH POL'Y, L. & ETHICS 191, 205 (2020) (Knox).

26. Historically, Congress employed a free-market approach based on market-driven prices to calculate Medicare reimbursements. Under Medicare Part B, Congress calculated reimbursement using a market-based "average sales price" methodology. *See* 42 U.S.C. § 1395w–3a; Knox at 203.

27. And when Congress created Medicare Part D in 2003, it prohibited HHS from "interfer[ing] with the negotiations between drug manufacturers" and buyers. 42 U.S.C. § 1395w–111(i)(1). "[I]ndividual Medicare Part D plans can and do negotiate prices with prescription drug manufacturers." Knox, *supra*, at 206. Plans are incentivized to do so because lower prices make it easier to secure Government approval for the plan, and render the plan more attractive to consumers. *See id.*

28. Congress established these market-based reimbursement systems because it recognized that pharmaceutical innovators depend on the revenues from the very small percentage of medicines that ultimately secure FDA approval and become marketable products in order to fund their research and development of a much larger volume of potential therapies, many of which never reach the market. The goal is to ensure that these companies can keep innovating and developing life-saving treatments for all Americans.

B. The Inflation Reduction Act.

29. By enacting the Program, the IRA fundamentally transforms the way the Government obtains and pays for prescription medicines under Medicare. As set forth below, the Program directs HHS to select certain medicines, dictate a discounted price for those medicines, and then coerce manufacturers using the threat of penalties disguised as "taxes" to sell the medicines at those discounted prices while declaring the terms to be "fair."

30. The new Program begins with drug selection. The Secretary must select 10 "negotiation-eligible" medicines by September 2023. 42 U.S.C. §§ 1320f(d), 1320f–1(a)(1). In February 2025 and February 2026, HHS must add 15 more medicines per year to the Program. *Id.* § 1320f–1(a)(2)–(3). Starting in February 2027, the Secretary must annually choose 20 new medicines to add. *Id.* § 1320f–1(a)(4).

31. This is a cumulative process, meaning new medicines are *added* to the Program each year. That is why projections show that half of all Medicare drug spending will be controlled by this new IRA price-setting process within ten years.

32. The selection of pharmaceuticals is based on total Medicare expenditures, with HHS choosing the products that cost the program the most over the prior year. *Id.* § 1320f–1(b)(1)(A). That selection mechanism ensures that the Program targets pharmaceutical companies' most successful products—those that are most valuable and most widely used—which are precisely the products the companies depend on to recoup their overall research and development investments.

33. Based on the statutory formula and publicly available data, HHS must and will select Eliquis, a groundbreaking BMS medicine used to prevent blood clots and strokes, as part of the first round of the Program in September 2023.

34. Independent analysts have also projected that HHS will select Opdivo, an immunotherapy developed by BMS that is widely used to treat various cancers, two years later. *See* Dickson & Hernandez, *supra*.

35. Once a medicine is chosen by HHS, its manufacturer is given 30 days to "enter" an "agreement[]" with the Secretary. 42 U.S.C. § 1320f–2(a). The "agreement" commits the manufacturer to participate in the Program's faux "negotiation" process and to reach agreement with HHS on a "maximum fair price" (MFP) for the drug. *Id.*

36. According to initial CMS guidance, that requirement will be effectuated through a signed agreement that sets forth the requirements governing participation in the Program. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 26 (Mar. 15, 2023) (CMS Initial Memo).

37. Importantly, however, if a manufacturer refuses to "agree" to engage in the faux "negotiation" process by that statutory deadline, it must pay an escalating daily penalty (which the Act refers to as an "excise tax") that starts at 186% and eventually reaches 1,900% of the drug's daily revenues. *See* 26 U.S.C. § 5000D; Cong. Rsch. Serv., Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) at 4, tbl. 2 (2022). That penalty guarantees compliance by making it exponentially more expensive to pay the penalty than to "agree" to the Government's terms. Notably, the penalty is based on the targeted product's revenues from *all* sources, not just Medicare.

38. So, if BMS were to refuse to participate in the Government's scheme, it could incur in excess of $150 million in "excise-tax" penalties on the very first day it declines to enter an "agreement" relating to Eliquis, escalating to *in excess of $1.5 billion* per day after a few months of such resistance.

39. Confirming that these draconian penalties exist only to coerce compliance (as no company could afford to pay them), Congress itself projected this "tax" to raise "no revenue"—a stark admission. Joint Comm. On Tax'n, Estimated Budget Effects of the Revenue Provisions Of Title XIII — Committee On Ways And Means, of H.R. 5376, The "Build Back Better Act," Fiscal Years 2022–2031, at 8 (Nov. 19, 2021).

40. Once the manufacturer faced with that untenable choice commits to "negotiate," the process begins with the Secretary providing a "written initial offer … and a concise justification." 42 U.S.C. § 1320f–3(b)(1)(B). Notably, the law does not limit how low a price HHS can dictate, but it does cap how high an amount HHS may set. That ceiling is imposed at a percentage of a benchmark market price known as the "non-federal average manufacturer price," or "non-FAMP." Under the Program, the Secretary is permited to "offer" no more than 75% of non-FAMP for newer medicines, and no more than 40% of non-FAMP for medicines that have been on the market for over 16 years. *See id.* § 1320f–3(b)(2)(F), (c)(1)(C). In other words, the Program mandates that the Government secure a discount of at least 25% to 60% from this market-based benchmark, with no floor beneath which HHS cannot go.

41. Adding insult to injury, the IRA purports to bar judicial and administrative review of HHS's decisions about what prices to offer. *See* 42 U.S.C. § 1320f–7.

42. While the Program permits the manufacturer to make a "counter-offer," it restricts the factors that can be used to justify any such "counter-offer." *Id.* § 1320f–3(b)(2)(C)(ii), (e). Among other things, although manufacturers can cite the research

and development costs for the particular product requisitioned by the Government, they cannot account for the enormous costs incurred in researching the exponentially larger number of medicines that never result in marketable therapies.

43. But even more problematic is that HHS is free to simply ignore any such "counter-offer" and dictate what price the manufacturer must "agree" to. In particular, the IRA says that negotiations "shall end" by a fixed date—for the first round, by August 1, 2024, *id.* § 1320f-3(b)—by which point the manufacturer must submit "a response" to the Secretary's "final written offer, either accepting or rejecting [it]." CMS Initial Memo at 54.

44. Although that process simulates a "negotiation," the key difference is this: If the manufacturer does not "accept" the HHS offer of whatever price the agency has announced to be "fair," then the company is once again subject to indefinite daily tax penalties that are designed to destroy the entire economic value of the product (and then some). *See id.* § 1320f–2(a)(1); 26 U.S.C. § 5000D.

45. In short, these are negotiations and agreements in name only. Indeed, the unconscionability and duress that serve as pillars of the Program would render the agreements unenforcable under any contractual analysis.

46. As part of the resulting "agreement," the manufacturer must commit to provide Medicare beneficiaries with "access" to the covered pharmaceutical product at the dictated price. 42 U.S.C. § 1320f–2(a)(1). Failure to do so triggers enormous civil monetary penalties. *See id.* § 1320f–6(a); § 1320f–6(c).

47. The IRA and its "agreements" therefore do not merely prohibit charging more than the HHS-dictated MFP; they compel the manufacturer to provide Medicare beneficiaries with "access" to the medicines while charging Medicare that discounted price. And that obligation extends indefinitely, unless and until HHS determines that a generic or biosimilar version of the product has been approved and marketed, *id.* § 1320f–1(c)(1), or the agency picks it for a similar "renegotiation," *id.* § 1320f–3(f).

C. The IRA's Threat to Innovation.

48. America's pharmaceutical companies, including BMS, are working to develop thousands of innovative new treatments. But there is no guarantee that those efforts will bear fruit. The research and development process requires tremendous investments in time, money, and experimentation. One study found that, on average, $2.5 billion in revenue is required to support the invention of one new drug product. *See* P. Dubois, et al., *Market Size and Pharmaceutical Innovation*, 46 RAND Journal of Econ. 844, 861 (2015).

49. Despite these massive investments, the vast majority of new research projects do not even result in testable products. Indeed, only a fraction of 1% of the projects that enter preclinical testing eventually secure FDA approval—and only a fraction of *those* rare success stories recoup their investment costs. *See* J. Vernon & J. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7–12 (2008). The ability to bring groundbreaking therapies to market thus depends on returns generated by just a handful of successful products.

50. Rather than encouraging BMS and other innovators to take the enormous risks necessary to bring life-saving medicines to patients who need them, the IRA penalizes those efforts. It targets precisely those rare breakthroughs that not only reach but revolutionize the market and become widely prescribed—and, thus, undergird and make possible the incredibly costly efforts to extend and improve human lives afflicted with disease.

51. As explained above, once such medicines have been on the market for a set period and have demonstrated their value to Medicare beneficiaries, the IRA will force manufacturers to sell them at Government-imposed discounted prices.

52. Given the sheer size of the Medicare market, this poses a grave and imminent threat to BMS's ability to fund new research. Again, the IRA places low price ceilings on such products, but no floors. As a result, manufacturers like BMS must operate—starting *now*—on the expectation that their most successful future products will be taken by the Government at well-below-market prices.

53. That impact on incentives is already rippling across the pharmaceutical industry. Research and development projects once deemed feasible are being abandoned, and the focus of research and development efforts are being skewed for reasons that have no connection to social welfare or patient health, but rather to the industry's survival.

54. For example, one manufacturer suspended development of a treatment for a rare eye disease because it would have fallen within the IRA's crosshairs. *See* J.

Grogan, *The Inflation Reduction Act is Already Killing Potential Cures*, WALL ST. J. (Nov. 3, 2022). Meanwhile, another company announced that, "in light of the [IRA]," certain blood cancer research "no longer met [the] threshold for continued investment." *Id.*

55. This pattern will only grow more pronounced in the years to come. One of America's great industries—a source of innovation the world depends on—will be seriously impaired. Life-saving treatments for diseases like cancer and Alzheimer's will remain undeveloped, and Americans will have fewer options to treat their most serious diseases.

D. The IRA's Uncompensated Taking of Property.

56. The basic premise of the Fifth Amendment's Takings Clause is that if the Government wants to appropriate private property—even for a legitimate, beneficial public use—it must pay "just compensation" to the owner. U.S. Const., amdt. V.

57. BMS's products are private "property" under that Clause. As the Supreme Court recently reaffirmed in a case involving appropriation of a share of raisin farmers' crops, "personal property" is just as "protected against physical appropriation" as "real property." *Horne v. Dep't of Agric.*, 576 U.S. 351, 358–59 (2015).

58. These medicines are also *patented*. A patent confers "exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation." *Id.* at 359; *see also Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) ("That a patent is property, protected against appropriation both by individuals and government, has long been settled.").

59. For both reasons, it is clear that the Government could not simply seize or appropriate a share of BMS's pharmaceutical inventory.

60. In effect, however, the IRA's scheme does the same thing. As explained above, the Program uses the threat of ruinous excise taxes to coerce BMS and other targeted manufacturers to transfer their patented pharmaceutical products to Medicare beneficiaries. Under the statute, BMS must provide "access" to those products—*i.e.*, turn them over. That compelled transfer is a classic, *per se*, physical taking of property because it deprives BMS of the "rights 'to possess, use and dispose of'" its property. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982).

61. To be sure, the IRA requires BMS to give its products to third parties (ultimately for the benefit of Medicare beneficiaries), not to the Government directly. But that does not make any legal difference. *See Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021) (taking occurs whether the Government takes property "for itself or someone else"). And, of course, the Government—as insurer—is the ultimate financial beneficiary.

62. It is also true that the IRA provides *some* compensation to manufacturers like BMS—the statutorily capped amount that HHS picks as the MFP. But the Fifth Amendment requires the Government to pay "just compensation," which the Supreme Court has made clear is "the fair market value of the property at the time of the taking." *United States v. Reynolds*, 397 U.S. 14, 16 (1970).

63. The IRA's price-setting mechanism bears no connection to fair market value. To the contrary, the IRA objectively and deliberately departs from measurable market value by compensating manufacturers at a minimum 25% discount (and, with no floor, perhaps far steeper) from non-FAMP. Securing that discount for the Government's benefit is precisely the point. These terms ensure the Government will requisition BMS's medicines without paying just compensation.

64. The specific MFP may ultimately bear on the amount of damages to which BMS is entitled, but it does not change the reality that the IRA effectuates a physical taking without providing just compensation. The same was true in *Horne*: The law there provided for potential compensation down the road, but the Supreme Court was clear that any such payment merely impacted the computation of damages. *See* 576 U.S. at 364.

65. In short, just as the statute in *Horne* effected a classic *per se* taking by requiring raisin farmers to turn over a portion of their crops to the Government, the IRA does the same by compelling pharmaceutical manufacturers to surrender their patented medicines to third parties for the Government's benefit. In both cases, "[t]he Government has a categorical duty to pay just compensation." *Id.* at 358.

E. The IRA's Compulsion To Speak.

66. As explained above, the Program does not involve genuine "negotiations" or voluntary "agreements," because it uses the threat of enormous penalties in order to induce the manufacturers to participate in the process and sign on the dotted line.

67. For political purposes, however, Congress chose to structure the Program to create the appearance of manufacturer consent. It would have been simple enough to authorize HHS to set maximum prices for covered medicines. But that would have exposed the IRA as a top-down set of price controls, which are not politically popular because of their association with shortages and health-care waiting times.

68. Indeed, while a recent poll found that 79% of Americans support "allowing the federal government to directly negotiate with drug companies to get a lower price on medications," support dropped by over 30 points when the respondents were asked about a regime that "effectively allow[s] the federal government to set the prices of drugs." National Tracking Poll #2109099, Morning Consult (Sept. 2021), at 13, 17.

69. That explains why the Government has consistently mischaracterized the Program as involving only voluntary negotiations and consensual agreements. The IRA's supporters frequently repeated that the statute envisions nothing more than voluntary dealmaking. And the President has since echoed this false characterization. On signing the IRA, the President claimed it gave Medicare merely "the power to negotiate lower prescription drug prices." Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022), ("[A]fter years of Big Pharma blocking it, Medicare will finally get the power to negotiate lower prescription drug prices."); *see also* State of the Union Address (Feb. 7, 2023) ("[The IRA] finally giv[es] Medicare the power to negotiate drug prices … bringing down prescription drug costs.").

70. Of course, the Government is free to spread its own messages and beliefs whether BMS agrees with them or not. But what the IRA cannot do is compel BMS to become a spokesperson for promoting the Government's value judgments.

71. That is just what the IRA does. Again, instead of just mandating that BMS and other companies sell at the dictated price, the statute compels them to engage in performative "negotiations" and "agreements." Those processes ultimately require manufacturers to endorse and express the viewpoint that they "agree" to HHS-dictated prices, and that those prices are "fair." 42 U.S.C. § 1320f–2(a), (a)(1).

72. This forced messaging promotes the impression that innovators acquiesce in prices that are actually imposed by HHS fiat and to which the companies *must* "agree" in order to avoid vast excise-tax penalties. That may advance a political agenda—letting the Government repeatedly tell the American public that everyone has agreed on lower "fair" prices—but it is legally impermissible under the First Amendment.

73. One of the core purposes of the First Amendment is to protect citizens (including businesses) from being forced to violate their convictions by espousing messages they reject. "At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). When the Government coerces a person into articulating views he rejects, that "invades the sphere of intellect and spirit" that the First Amendment "reserve[s] from all official control." *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943).

74. The First Amendment also serves to ensure a transparent marketplace of ideas by shielding open public debate from state distortions. When Congress "requires the utterance of a particular message favored by the Government," it "seeks not to advance a legitimate regulatory goal, but to … manipulate the public debate through coercion." *Turner Broad.*, 512 U.S. at 641. The First Amendment prevents corruption of "the processes through which political discourse or public opinion is formed." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 49 (2017) (Breyer, J., concurring).

75. The IRA's negotiation-and-agreement regime violates those principles. By forcing manufacturers to "agree" with HHS on a "maximum fair price," the Program compels those businesses to parrot an ideological message inimical to their own views. *See* 42 U.S.C. § 1320f–2(a)(1); CMS Initial Memo 27, 54.

76. BMS understands from over a century and a half of industry experience that its medicines must be priced to support the incredibly expensive process of researching, developing, and securing FDA approval for life-saving medicines—most of which never become marketable products. The "fairness" of a price must be informed by these economic realities. Accordingly, BMS does *not* "agree" that forced sales at innovation-stifling discounts are "fair" to anyone, least of all patients.

77. But to avoid massive liability, BMS must promote the Government's counternarrative. That is antithetical to the First Amendment, under which BMS cannot be made a "vehicle for spreading a message with which it disagrees." *Pac. Gas & Elec. Co. v. Pub. Utilities Comm'n of Cal.*, 475 U.S. 1, 17 (1986) (plurality).

78. The IRA's contrived display of "agreements" also distorts public debate by bolstering and insulating the message that HHS's prices are "fair." Again, the Government is entitled to persuade the public that drug prices would be "unfair" absent the IRA. But the Government cannot compel regulated parties to feign agreement with the Program's aims or to broadcast its supposed benefits.

79. Even if BMS or others could engage in a media campaign to counter the false message conveyed by these coerced "agreements," the Supreme Court has long held that "the government [cannot] require speakers to affirm in one breath that which they deny in the next." *Id.* at 16; *see also Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 471 (1997) (compelled speech violates the First Amendment if it forces company "to respond to a hostile message"). That itself burdens the freedom of speech.

80. Further underscoring the IRA's deceptive goals, CMS has announced that its "negotiations" will be held in secret, with manufacturers subject to a gag order. CMS has ordered that manufacturers "shall not disclose to the public any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, … any information contained in any concise justification provided with an offer[,] [or] … any information exchanged verbally during the negotiation period." CMS Initial Memo 30. CMS will also "prohibit audio or video recording of any oral conversations between CMS and a … Manufacturer." *Id.* Manufacturers will thus be barred from informing the public as to how these faux "negotiations" actually proceed. That confirms the goal of misleading the public about the true nature of this pricing regime.

81. Because the IRA compels speech, it must satisfy heightened scrutiny to survive. But these speech burdens do not advance any legitimate (much less substantial or compelling) government interest. Deceiving the public does not reduce prices, advance innovation, or protect the public fisc. Unlike safety warnings or other purely factual and uncontroversial compelled disclosures, there is no public health interest in running the IRA's mandates through a set of "agreements."

82. Congress could have sought to accomplish its *economic* goals by simply empowering HHS to use its purchasing power to reach genuine agreements, or even to unilaterally impose price caps that Medicare would pay for covered medicines. The Act's structure is instead driven entirely by politics and perception—as its rollout attests. The Government has trumpeted this new opportunity to "negotiate" lower prices. After all, Americans expect their Government to advance their interests at bargaining tables of all sorts—from corporate boardrooms to international summits.

83. But there is no genuine bargain here—just empty slogans that companies are compelled to communicate. That violates the First Amendment.

F. The IRA Does Not Impose Lawful "Conditions" on Medicare.

84. These constitutional violations cannot be excused by pointing out that pharmaceutical manufacturers can theoretically avoid the IRA's tax penalties by simply exiting the Medicare and Medicaid programs. That misapprehends the nature of Congress's Spending Power and the careful limits that the Supreme Court has imposed to prevent its abuse.

85. For one thing, while Congress may impose conditions on private entities that accept federal funds, "if Congress intends to impose a condition on the grant of federal moneys, it must do so *unambiguously*." *Cummings v. Premier Rehab Keller, P.L.L.C.*, 142 S. Ct. 1562, 1570 (2022) (emphasis added). That ensures the "recipient voluntarily and knowingly accept[ed] the terms" offered by the Government. *Id.*

86. Here, the IRA does not set forth conditions on Medicare or Medicaid reimbursement, or provide for exclusion from those benefit programs if a manufacturer does not cooperate. Rather, the statute commands manufacturers to comply and levies monetary penalties for failure to do so. On the back end, the statute "suspends" its tax penalty if a manufacturer has completely extricated itself from both Medicare and Medicad—not merely for the product at issue but for *all* of its products. 26 U.S.C. § 5000D(c). But that indirect, convoluted scheme does not "unambiguously" condition a manufacturer's receipt of federal funding on its acceptance of the IRA's mandates.

87. For another thing, even this choice is illusory. BMS will be compelled, under threat of nine- and ultimately ten-figure daily excise-tax penalties, to sign an agreement submitting to forced sales of Eliquis by October 1, 2023. Yet the IRA delays a manufacturer's ability to terminate its Medicare participation for between 11 and 23 months. 42 U.S.C. § 1395w–114a(b)(4)(B)(ii). Thus, to avoid being penalized for failure to sign the October 1 "agreement," BMS would have needed to withdraw by January 31, 2022—*months before the IRA was even enacted*. This timeline confirms that the IRA imposes mandates and employs threats; it does not set true "conditions."

88. Finally, conditioning the receipt of Medicare payments on abandonment of First and Fifth Amendment rights is unconstitutional. Under the doctrine of unconstitutional conditions, the Government may condition a benefit on forfeiture of a property right only if doing so substantially advances a purpose related to that benefit, and is "rough[ly] proportiona[l]" to it. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994).

89. Here, due to the interlinked nature of federal insurance programs, *see* 42 U.S.C. §§ 1395w–153(a)(1), 1396r-8(a)(1), (c), for a manufacturer to extricate itself from the IRA's tax penalty would preclude it from receiving *any* payments for *any* medicines reimbursed by Medicare Part B, Medicare Part D, or Medicaid.

90. Coercing sales of *one* pharmaceutical product at discount prices does not substantially advance the purposes of countless other transactions whereby Medicare and Medicaid pay for *different* products. Leveraging the Government's market power over certain transactions to coerce terms on an entirely distinct transaction is an abuse of the Spending Clause. *See Harris v. McRae*, 448 U.S. 297, 317 n. 19 (1980) (noting "substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits" based on exercise of a constitutional right).

91. Moreover, this alleged condition is plainly not "rough[ly] proportiona[l]" under *Dolan*, 512 U.S. at 391. Just the opposite—it is cross-collateralized in a way that makes clear that the Government's objective is to deter and penalize manufacturers' refusal to forfeit their rights.

92. In short, the IRA's threat is unconstitutionally coerceive—a "gun to the head"—because it leverages vast, unrelated benefits to induce the transactions that the Government wants. *Nat'l Fed'n of Indep. Business v. Sebelius*, 567 U.S. 519, 581 (2012) (*NFIB*). Medicare and Medicaid account "for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Withdrawing from half of the U.S. prescription drug market, leaving tens of millions of patients without their medications, is simply not a tenable option. Nor is holding hostage access to half of the U.S. pharmaceutical market a legitimate condition. It is instead "'economic dragooning'" amounting to "'a gun to the head.'" *Doe v. Univ. of Sciences*, 961 F.3d 203, 213 (3d Cir. 2020) (quoting *NFIB*, 567 U.S. at 581–82).

CLAIMS

Count One: Uncompensated Takings (Fifth Amendment)

93. BMS realleges all prior and subsequent paragraphs.

94. The Fifth Amendment requires the Federal Government to pay "just compensation" when it takes private property. U.S. Const. amend. V.

95. BMS's patented pharmaceutical products, including Eliquis and Opdivo, are protected personal property under the Fifth Amendment and Takings Clause.

96. The IRA will requisition those products and transfer them to Medicare beneficiaries. Those forced sales—coerced by the threat of draconian penalties that the Government has admitted no manufacturer could ever afford to pay—will deprive BMS of possession and title to its personal property. That is a *per se* taking.

97. That triggers "a categorical duty to pay just compensation." *Horne*, 576 U.S. at 358. "[J]ust compensation" requires the Government to pay the fair market value of medicines that it appropriates. *Reynolds*, 397 U.S. at 16. The IRA, however, requires HHS to arrogate discounts that necessarily fall below market value, and grants the agency unchecked discretion to provide even less remuneration. The entire purpose of the Act is to secure medicines like Eliquis for Medicare beneficiaries at heavily discounted prices, so the Government—the ultimate payor—can save money. The statute is thus designed specifically *not* to provide just compensation.

98. Declaratory relief is "appropriate." 28 U.S.C. § 2201. Declaratory relief for takings claims is available when a statute does not provide "advance assurance of adequate compensation in the event of a taking." *Duke Power Co. v. Envt'l Study Grp.*, 438 U.S. 59, 71 n.15 (1978).

99. Declaratory relief is also appropriate because an *ex post* suit for damages would be "utterly pointless," as "Congress could not have contemplated" that "every dollar [saved] pursant to the [IRA] would be presumed to generate a dollar of … compensation." *E. Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality).

100. Moreover, declaratory relief is appropriate where it would "resolve the uncertainty" that "gave rise to the controversy"; promote "convenience of the parties," especially relative to "other remedies" that may be available; and further "the public interest." *Reifer v. Westport Ins. Corp.*, 751 F.3d 129, 140 (3d Cir. 2014). All of those criteria are satisfied here.

101. Accordingly, the Court should declare that the Program will effect takings of BMS's private property without providing for "just compensation" under the Fifth Amendment.

Count Two: Compelled Speech (First Amendment)

102. BMS realleges all prior and subsequent paragraphs.

103. The First Amendment protects both the right to speak and the right to refrain from speaking. *See Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013). Laws that compel private speech are presumptively unconstitutional and may stand only if narrowly tailored to serve compelling interests.

104. The IRA will compel BMS to speak by forcing it to communicate that it has "agreed" to an HHS-mandated price, and to endorse the view that HHS's price is "maximum fair price" for the medicine. BMS does not agree with those statements or the value judgments they reflect.

105. The Government's only apparent interest in compelling this speech is to reap political benefits by camouflaging forced sales as voluntary negotiations. Indeed, Congress could have authorized HHS to genuinely negotiate (or even unilaterally set) prices, or capped the prices at which manufacturers could sell their medicines, without sham "negotiations" or "agreements" coerced by tens or hundreds of millions of dollars in daily fines. The IRA's convoluted alternative regime appears designed to mislead the public, evade accountability, and promote an attractive political slogan. That is neither a compelling nor a legitimate government interest.

106. An injunction is necessary. "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976). And because the Government can offer no legitimate justification for the IRA's performance art, the equities and the public interest also favor a permanent injunction against the IRA's compelled "agreements."

107. The Court should declare that the IRA's requirements that manufacturers "agree" to "maximum fair prices" are unconstitutional and enjoin Defendants from enforcing them. In particular, the Court should enjoin Defendants from forcing BMS to sign an initial "[m]anufacturer agreement[]," 42 U.S.C. § 1320f–2(a), or to "agree to" a "maximum fair price" developed through the Program. *See id.* § 1320f–2(a)(1), (a)(2). And the Court should declare null and void any such agreements that BMS may be unconstitutionally coerced to enter before this case is adjudicated.

PRAYER FOR RELIEF

Now, therefore, BMS requests a judgment in its favor as follows:

1. Declaring that the Program effects takings without assuring the provision of just compensation under the Fifth Amendment;

2. Declaring that the Program compels speech in violation of the First Amendment;

3. Enjoining Defendants from forcing BMS to sign an initial "manufacturer agreement" or to "agree" to prices set by the Program;

4. Declaring any such agreements that BMS has been compelled to enter under the IRA's unconstitutional threat of penalties to be null and void;

5. Awarding reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and

6. Granting such other and further relief as the Court may deem appropriate.

Dated: June 16, 2023

Respectfully submitted,

s/ Jennifer L. Del Medico
Toni-Ann Citera*
Jennifer L. Del Medico
Rajeev Muttreja*
JONES DAY
250 Vesey Street
New York, NY 10281
(212) 326-3939

Noel J. Francisco*
Yaakov M. Roth*
Brett A. Shumate*
John Henry Thompson*
Louis J. Capozzi III*
JONES DAY
51 Louisiana Avenue N.W.
Washington, DC 20012
(202) 879-3939

**pro hac vice* application forthcoming

Counsel for Plaintiff
Bristol Myers Squibb Company

SILLS CUMMIS & GROSS P.C.
Jeffrey J. Greenbaum
Katherine M. Lieb
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

JONES DAY
Toni-Ann Citera*
Rajeev Muttreja*
250 Vesey Street
New York, NY 10281
(212) 326-3939

**pro hac vice* application pending

JONES DAY
Noel J. Francisco*
Yaakov M. Roth*
Brett A. Shumate*
Charles E.T. Roberts*
51 Louisiana Ave. NW
Washington, DC 20012
(202) 879-3939

Attorneys for Plaintiff
Bristol Myers Squibb Company

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB COMPANY, Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services; *et al.*, Defendants.	:	Civil Action No. 23-3335(ZNQ)(JBD) Hon. Zahid N. Quraishi Hon. J. Brendan Day **DECLARATION OF CHRISTOPHER T. MANCILL**

I, Christopher T. Mancill, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Senior Vice President and Head of Worldwide Value Access & Payment ("VAP") and Health Economics & Outcomes Research ("HEOR") at Bristol Myers Squibb Co. ("BMS"). I submit this declaration in support of BMS's Motion for Summary Judgment. Because this Declaration is provided by BMS, the information set forth in the Declaration is not necessarily all within my personal

knowledge or within the personal knowledge of any single individual but includes information assembled by authorized employees and/or counsel of BMS, upon whom I have relied. Subject to these limitations, the facts contained in the Declaration are true and correct to the best of my knowledge, information, and belief.

2. I have been employed by BMS for over 2 years. In my current role, I am responsible for, among other things, BMS's operations relating to the Inflation Reduction Act's ("IRA") "Medicare Drug Price Negotiation Program" (the "Program"). I report to Adam Lenkowsky, Executive Vice President and Chief Commercialization Officer.

The Program Will Cover BMS's Products.

3. BMS invests billions of dollars every year to research and develop medicines to address the unmet medical needs of patients with serious diseases. Only a small percentage of those potential products ultimately secure FDA approval and are successfully marketed.

4. BMS developed and markets Eliquis (apixaban), a groundbreaking medicine used to prevent blood clots and strokes. Eliquis is a novel oral anticoagulant, which works by inhibiting a blood-clot-forming substance called Factor Xa.

5. On December 28, 2012, the United States Food and Drug Administration ("FDA") first approved Eliquis to reduce the risk of stroke and blood clots in patients with non-valvular atrial fibrillation.

6. On March 18, 2014, the FDA approved Eliquis to reduce the risk of blood clots in the legs and lungs of people who have just had hip or knee replacement surgery.

7. On August 21, 2014, the FDA expanded Eliquis's label once more to include treatment for deep vein thrombosis (blood clots in the legs) or pulmonary embolism (blood clots in the lungs) and to reduce the risk of those conditions occurring again.

8. BMS has been a leader in cardiovascular clinical research, having conducted more than 40 clinical trials with Eliquis involving tens of thousands of patients with cardiovascular illness. As of July 2023, approximately 140 trials studying Eliquis across a wide variety of conditions and treatment settings have been recorded in the ClinicalTrials.gov database.

9. Since 2013, over 110 million prescriptions for Eliquis have been filled in the United States.

10. BMS has obtained multiple patents securing its intellectual property in Eliquis, including patents that remain operative today. The FDA first approved Eliquis on December 28, 2012. For these reasons, Eliquis will be a "qualifying single source drug" under the IRA. *See* 42 U.S.C. § 1320f–1(e)(1)(A).

11. Based on past and current spending levels within Medicare, Eliquis will be subject to the Program in September 2023, when the Department of Health and Human Services ("HHS") announces the first set of covered drugs.

12. BMS also developed and markets Opdivo (nivolumab), a medicine used to treat several types of cancer. Opdivo works by binding to a certain protein, called PD-1, to help immune cells kill cancer cells.

13. On December 22, 2014, the FDA first approved Opdivo to treat advanced melanoma.

14. A few months later, on March 4, 2015, the FDA approved Opdivo to treat patients with advanced squamous non-small cell lung cancer.

15. After those first two approvals, the FDA expanded Opdivo's label twenty-six more times over the subsequent seven years, including for additional types of melanoma and small cell lung cancer, as well as for indications in renal cell carcinoma, Hodgkin lymphoma, head and neck cancer, urothelial carcinoma, colorectal cancer, hepatocellular cancer, esophageal carcinoma, mesothelioma, and gastric cancer.

16. Indeed, BMS has been a leader in clinical research on cancer treatments, having conducted more than 450 clinical trials involving more than 150,000 cancer patients over the past 15 years. As of July 2023, approximately 1,600 trials studying Opdivo across a wide variety of conditions and treatment settings have been recorded in the ClinicalTrials.gov database.

17. Since 2015, over 400,000 patients have been treated with Opdivo in the United States.

18. BMS has obtained multiple patents securing its intellectual property in Opdivo, including patents that remain operative today. The FDA first approved Opdivo on December 22, 2014. For these reasons, Opdivo will be a "qualifying single source drug" under the IRA. *See* 42 U.S.C. § 1320f–1(e)(1)(A).

19. Based on current and expected spending levels within Medicare, Opdivo will be selected in a subsequent cycle of the Program.

The Program Will Compel BMS To Convey Views That It Rejects

20. Once HHS selects a product for the Program, BMS will have 30 days to "enter into" a "manufacturer agreement" with HHS. 42 U.S.C. § 1320f–2(a). That document, which HHS will make public, will convey BMS's "agreement" to participate in the Program's "negotiations," and that BMS "agree[s]" both to HHS's dictated prices and that such prices are what the IRA calls the "maximum fair price." BMS will then have to sell its drugs at that price or risk daily penalties of up to 1,900% of the revenues of the covered drug. *See* 26 U.S.C. § 5000D. The Centers for Medicare & Medicaid Services will effectuate this requirement through a signed "agreement" setting forth the requirements governing participation in the Program.

21. BMS will therefore be compelled to communicate publicly that it is voluntarily entering into *bona fide* negotiations with HHS and, at the end of that process, that those negotiations culminated in an agreed-upon price that BMS considers "fair."

22. BMS rejects every premise behind the IRA's "manufacturer agreement" and the messages it compels BMS to communicate.

23. *First*, BMS *dis*agrees that the Program will entail *bona fide* price "negotiations." To the contrary, HHS holds complete control over this process. The IRA sets a price ceiling well below the drug's market value. *See* 42 U.S.C. § 1320f–3(c) (setting ceiling price at no more than 40% to 75% of non-federal average manufacturer price). While the IRA allows BMS to submit a "counteroffer" to HHS, HHS is free to ignore that counteroffer in its final decision. At both the beginning and the end, HHS's price-setting discretion is unconstrained. And, of course, failure to reach agreement on HHS's terms triggers a severe tax penalty. The Program therefore does not resemble anything like the "negotiations" BMS undertakes in the ordinary course of business.

24. *Second*, BMS rejects the mischaracterization in the "manufacturer agreement" that BMS's participation in the Program's "negotiations" is voluntary. By design, massive penalties will coerce BMS's execution of the "manufacturer agreement" and participation in the "negotiation" process. If BMS declines to "agree" to negotiate, it will incur an escalating daily "excise tax" that starts at 186% and eventually reaches 1,900% of the drug's daily revenues from all sources. For Eliquis, that would mean a tax bill of hundreds of millions of dollars on the very first day of refusal to enter an "agreement," and it would soon escalate to over a billion dollars per day. Accordingly, BMS will have no choice but to sign a "manufacturer

agreement" despite its deep-seated opposition to the "agreement" content, aims, and messages.

25. *Third*, BMS rejects the message manifested in the "manufacturer agreement" that the Government-mandated price at the end of the "negotiation" process is the "maximum fair price." BMS does not wish to convey that viewpoint, which is contrary to its own views. BMS strongly believes that its products' pricing must support and compensate for the staggering expense of researching, developing, and obtaining regulatory approval for groundbreaking products, like the three approvals for Eliquis and the twenty-eight approvals for Opdivo. But the IRA's characterization of HHS's preferred price as the maximum "fair" price flatly contradicts BMS's true beliefs. Imposing below-market prices is not "fair" to anyone—including patients who rely on the development of new life-saving drugs.

26. After BMS's signature (under pain of massive penalties) is coerced, the "negotiation" process will commence. HHS will start with an "initial offer" subject only to the IRA's requirement that the "offer" represent a discount of at least 25% to 60% off market value, with potentially even greater discounts determined in HHS's sole discretion. 42 U.S.C. § 1320f–3(C). BMS must accept HHS's offer or submit a "counteroffer" within 30 days. Then, HHS remains free to keep to the same price contained in its "initial offer."

27. The Program's first round of this process "shall end" by August 1, 2024—11 months after HHS announces Eliquis's selection. At that time, BMS must respond to HHS's final offer.

28. BMS must "accept" that offer—or, as the IRA states, "agree to" HHS's final "maximum fair price." *See* 42 U.S.C. § 1320f–2(a)(1). If BMS does not accept the final offer and agree that it is "fair," BMS will incur the same unending and unlimited daily penalties it would by failing to enter the original "manufacturer agreement." *See* 26 U.S.C. § 5000D.

29. Again, BMS rejects every premise behind this final "agreement" to sell at the Government's "fair price" and every message it compels BMS to communicate.

30. *First*, as explained above, draconian penalties will force BMS to comply with HHS's final decision, so describing this final step as an "agreement" will falsely communicate that the parties have reached a meeting of the minds through good-faith negotiations.

31. *Second*, an "agreement" requires and therefore necessarily communicates voluntariness. That too is false, because there is nothing voluntary about succumbing to the IRA's coercion.

32. *Third*, nothing about HHS's dictated price is "fair." As explained above, that position, which the IRA compels BMS to communicate, is contrary to everything BMS believes and knows about its industry and products.

33. BMS's compelled participation in the Program will force the company to serve as a spokesperson for the Government's preferred messages—messages with which BMS fundamentally disagrees.

The Program Will Compel Forced Sales of BMS's Products.

34. Once the Program's "negotiations" have resulted in BMS's compelled agreement to sell its drugs at a price far below market, BMS must provide eligible individuals and entities participating in Medicare "access to such price." 42 U.S.C. § 1320f–2(a)(1). Here again, the IRA coerces BMS: Civil monetary penalties of ten times the difference between the price charged and the mandated price, *id.* § 1320f–6(a), plus an additional penalty for violation of the negotiated price "agreement," *id.* § 1320f–6(c), are the sanction for failing to transfer the product indefinitely at the Government-mandated price. BMS will have no choice but to accede to such forced sales.

35. These forced sales must continue at HHS's dictated price (increased only to account for inflation) until HHS reaches either of two determinations: (1) that a generic or biosimilar version of the drug has been approved and marketed, *id.* § 1320f–1(c)(1), or (2) that the drug is selected for "renegotiation" through essentially the same process, *id.* § 1320f–3(f)(2). Accordingly, BMS will be forced to indefinitely sell its drugs at massive discounts. Practically speaking, the Program compels BMS to transfer its property to others at a fraction of fair market value.

BMS's Participation in the Program Is Not Voluntary.

36. BMS entered Medicare Part D based in part on explicit congressional reassurance that market forces would determine drug prices under the program. *See* 42 U.S.C. § 1395w–111(i). Neither Congress nor HHS presented the IRA's Program to BMS as a condition on participation in or reimbursement through Medicare or Medicaid. Thus, BMS had no notice that anything like the Program or its penalties would be part of entering Medicare Part D.

37. BMS could avoid the IRA penalties' coercive threat only by terminating *all* of its Medicare Part D manufacturer-discount agreements and Medicaid rebate agreements. *See* 26 U.S.C. § 5000D(c). But doing that would preclude BMS from receiving *any* payments for *any* drugs reimbursed by Medicare Part B, Medicare Part D, or Medicaid—and leave patients without access to critical medicines. In other words, BMS must go along with the Program or sacrifice access to nearly half of the U.S. prescription drug market.

38. That is no choice at all, when the only alternative would leave over 3 million current patients without access to vital medications and cost the company billions in revenue. Thus, BMS will have to remain subject to the Program not voluntarily, but rather because of the IRA's intended overwhelming coercion.

39. Moreover, Congress designed the IRA to prevent companies from withdrawing from Medicare in time to avoid the first round of price mandates. BMS will be compelled to sign an agreement submitting to forced sales of Eliquis by

October 1, 2023. But Congress provided that a manufacturer's termination of its Medicare Part D agreements is effective only after 11 to 23 months. *See* 42 U.S.C. § 1395w–114c(b)(4)(B)(ii). Thus, under Congress' design, to avoid penalties for failure to sign the October 1 "agreement," BMS would have needed to terminate all relevant Medicare and Medicaid contracts by January 31, 2022—months before the IRA was even enacted. BMS did not, and could not, know to do so.

The Program Will Harm Both BMS and the Nation.

40. The Program will severely curtail BMS's ability to develop innovative medicines for patients with unmet medical needs. The United States is the beating heart of lifesaving pharmaceutical innovation because of BMS and companies like it. Drugs like Eliquis and Opdivo—hallmarks of the sector's extraordinary capabilities—improve and extend the lives of tens of millions of Americans in ways once thought impossible. Developing such breakthrough cures and therapies requires BMS to invest billions of dollars, and the reality is that only a small percentage of investigated drugs will reach FDA approval, let alone recoup their true development costs.

41. Charging market prices for that tiny class of drugs that not only make it to market, but achieve groundbreaking results, is therefore crucial for BMS to continue to innovate. Because the IRA targets *exactly* those rare drugs for Government-imposed price caps, the Program will substantially hinder BMS and its peers as they pursue that life-saving work. Indeed, as a result of the IRA, BMS

recently made the difficult decision not to pursue a registrational study of its drug iberdomide in newly diagnosed multiple myeloma patients.

42. The realities of cutting-edge cancer research and development illustrate the IRA's devastating consequences. Generally, new cancer treatments are first deployed to combat late-stage metastatic disease, and a manufacturer transitions a new treatment to earlier stages only after it proves successful in treating late-stage cancer. That is due, in part, to risk-benefit considerations, which are initially most favorable for patients facing the worst prognoses. But the IRA's countdown to selection for price "negotiations" begins when a drug is initially *approved*. So by the time a drug proves itself as a late-stage treatment, suggesting the value of early-stage trials, the IRA will have decimated its profitability. Thus, the IRA will significantly impair BMS's efforts to further invest in available therapies that have the potential to become major breakthroughs in early cancer intervention, or for additional cancers.

43. Indeed, securing approval for new uses of established products will become (often prohibitively) more difficult in light of the IRA. Many pharmaceutical breakthroughs have entered the market as such new uses when researchers find through post-approval research and trials that a drug approved to treat one condition has equivalent or perhaps greater benefits as a treatment for a different disease. Indeed, this is often the more cost-effective route to approval, because the initial approval will have given the manufacturer extensive evidence regarding the drug's pharmacokinetics, toxicology, safety and efficacy, and the like. But the IRA

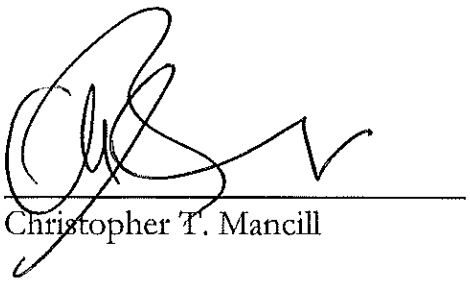
discourages post-approval research and development for the most successful drugs in a manufacturer's portfolio.

44. Take Opdivo as an example: It was first approved for metastatic melanoma in 2014 and went on to receive indications in ten additional cancers as well as additional forms of melanoma over the course of seven-plus years. However, once such a drug has been approved for *any purpose* for 9 years (for small-molecule drugs like Eliquis) or 13 years (for biologics like Opdivo), the IRA's price mandates will eliminate much of the manufacturer's potential return on its investments.

45. The Program's coercion will thus cause several devastating consequences: BMS will suffer enormous economic injuries and be forced to give up its property at substantial discounts, to the ultimate detriment of patients with serious diseases; BMS will be forced to curtail critical research for life-saving medicines; and it will also be forced to publicly convey Government messages with which it strongly disagrees. There is no voluntariness here, because the IRA's threat of enormous excise tax and civil penalties will compel BMS's acquiescence. So too will the ruinous consequences of entirely withdrawing from Medicare and Medicaid. Relief in this suit represents the only way to prevent BMS's imminent, irreparable injuries and vindicate its rights under the First and Fifth Amendments.

46. I declare under penalty of perjury that the foregoing is true and correct.

Executed: July 21, 2023



Christopher T. Mancill

SILLS CUMMIS & GROSS P.C.
Jeffrey J. Greenbaum
Katherine M. Lieb
One Riverfront Plaza
Newark, New Jersey 07102
(973) 643-7000

JONES DAY
Toni-Ann Citera*
Rajeev Muttreja*
250 Vesey Street
New York, NY 10281
(212) 326-3939

*admitted *pro hac vice*

JONES DAY
Noel J. Francisco*
Yaakov M. Roth*
Brett A. Shumate*
Charles E.T. Roberts*
51 Louisiana Ave. NW
Washington, DC 20012
(202) 879-3939

Attorneys for Plaintiff
Bristol Myers Squibb Company

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB COMPANY, Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services; *et al.*, Defendants.	:	Civil Action No. 23-3335(ZNQ)(JBD) Hon. Zahid N. Quraishi Hon. J. Brendan Day **DECLARATION OF TONI-ANN CITERA IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

I, Toni-Ann Citera, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am an attorney at Jones Day and counsel for Plaintiff Bristol Myers Squibb Company. I am over the age of 18 and have personal knowledge of the facts set forth here.

2. Attached as **Exhibit A** is a true and correct copy of a document issued on June 30, 2023, by the Centers for Medicare and Medicaid Services (CMS), entitled

"Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." It was accessed via CMS's website on July 19, 2023, at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

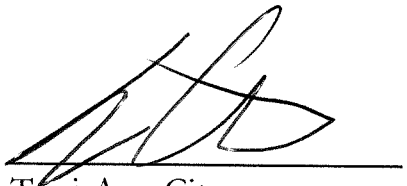
3. Attached as **Exhibit B** is a true and correct copy of the template "Medicare Drug Price Negotiation Program Agreement," issued by CMS and accessed via CMS's website on July 19, 2023, at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

4. Attached as **Exhibit C** is a true and correct copy of a memorandum issued on March 15, 2023, by CMS, entitled "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments." It was accessed via CMS's website on July 19, 2023, at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

5. Attached as **Exhibit D** is a true and correct copy of a study entitled *Drugs likely subject to Medicare negotiation, 2026–2028*. The study was published in March 2023 by the Journal of Managed Care and Specialty Pharmacy. It was accessed via the Journal's website on July 19, 2023, at https://www.jmcp.org/doi/10.18553/jmcp.2023.29.3.229?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 16, 2023



Toni-Ann Citera

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: June 30, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026

This memorandum provides interested parties with the revised Medicare Drug Price Negotiation Program guidance for initial price applicability year 2026. It includes four sections:

A. An introduction, which begins on page 1.
B. A summary of changes and clarifications to the initial memorandum released on March 15, 2023, which begins on page 2.
C. A summary of the public comments received in response to the initial memorandum, and the Centers for Medicare & Medicaid Services' (CMS') responses, which begins on page 8.
D. Revised guidance that establishes final policies on the topics discussed for initial price applicability year 2026, which begins on page 92 and for which a table of contents appears on page 94.

CMS may supplement this guidance with further program instruction to explain how these policies will be implemented during initial price applicability year 2026 (e.g., technical instructions for data submissions).

A. Introduction

Sections 11001(c) and 11002(c) of the Inflation Reduction Act (IRA) direct the Secretary to implement the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, on March 15, 2023, CMS issued an initial memorandum for implementation of the Negotiation Program for initial price applicability year 2026. CMS also voluntarily solicited comments on a number of key aspects of the initial memorandum. The 30-day comment period for the initial memorandum began March 15, 2023 and concluded April 14, 2023. CMS received more than 7,500 comment letters in response to the initial memorandum, representing a wide range of views from academic experts and thought leaders, consumer and patient organizations, data vendors/software technology entities, health plans, health care providers, health systems, individuals, labor unions, pharmaceutical and biotechnology

manufacturers, pharmacies, pharmacy benefit managers (PBMs), state governments, trade associations, venture capital firms, and wholesalers.

CMS will make public copies of the timely comment letters that CMS received on the Inflation Reduction Act website at https://www.cms.gov/inflation-reduction-act-and-medicare in July 2023. Comment letters from individuals not representing organizations will have the name, address, and contact information of the individual removed for privacy purposes. Additionally, substantively duplicative letters (e.g., submitted as part of a coordinated advocacy campaign) will be combined into a single document.

After consideration of the comments received, CMS is making certain changes to the policies described in the initial memorandum in this revised guidance for initial price applicability year 2026. These comments also may be considered in development of program guidance for initial price applicability years 2027 or 2028 of the Negotiation Program, for which CMS also intends to solicit comments. CMS will develop its policies for 2029 and all subsequent initial price applicability years of the Negotiation Program through notice-and-comment rulemaking. The public will have an additional opportunity to submit comments as part of that rulemaking process, and comments submitted in response to the initial memorandum may be considered as part of that rulemaking process.

CMS is providing a summary of significant comments that it received in response to the initial memorandum, as well as the agency's response to those significant comments, which begins on page 8. CMS is not responding in this document to all 7,500 comments that it received, but instead is addressing those significant comments that have prompted a revision or a clarification of its policies under the Negotiation Program, or that otherwise raised a significant issue warranting a response that would explain to the public the agency's resolution of that question.

B. Summary of Changes and Clarifications in Revised Medicare Negotiation Guidance

CMS received many constructive, thoughtful, and helpful comments from consumer and patient groups, manufacturers, pharmacies, individuals, and other interested parties on the initial Medicare Drug Price Negotiation Program Guidance that was released on March 15, 2023. This section provides a summary of the key changes and clarifications made to the initial memorandum based on these comments and other feedback. CMS provides responses to the comments received in section C of this revised guidance and has made corresponding changes and clarifications to the policies described in the initial memorandum, as summarized below.

Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2026: In section 30 of this revised guidance, CMS has made clarifications to policies detailed in section 30 of the initial memorandum, including:

- Bona Fide Marketing of a Generic Drug: CMS has clarified in section 30.1 of this revised guidance the process it will use to determine if bona fide marketing of a generic drug or biosimilar competitor to a potential qualifying single source drug is occurring for the purposes of drug selection. CMS will review both Prescription Drug Event (PDE) data and Average Manufacturer Price (AMP) data reported by manufacturers. The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be based on a totality of the circumstances, including PDE and AMP data.

- Orphan Drug Exclusion: CMS has clarified in section 30.1.1 of this revised guidance that a drug that has designations from the U.S. Food and Drug Administration (FDA) for more than one rare disease or condition will not qualify for the Orphan Drug Exclusion, even if the drug has not been approved for any indications for the additional rare disease(s) or condition(s) and that CMS will only consider active designations and active approvals when evaluating a drug for the Orphan Drug Exclusion; that is, CMS will not consider withdrawn orphan designations or withdrawn approvals as disqualifying a drug from the Orphan Drug Exclusion. CMS does not have the statutory authority to change the starting date from which qualifying single source drug status is determined, regardless of whether the drug or biological product was previously eligible for the Orphan Drug Exclusion under 1192(e)(3)(A) of the Social Security Act ("the Act").
- Exception for Small Biotech Drugs and Biosimilar Delay: CMS has clarified in sections 30.2.1 and 30.3.1 of this revised guidance the scope of the data that CMS will use to calculate the Small Biotech Drug Exception, which patents and litigation will be considered related to the Biosimilar Delay determination and how CMS will evaluate the manufacturing schedule for the marketing of the Biosimilar, as well as how, for both the Small Biotech Exception and the Biosimilar Delay, CMS will protect information from disclosure and communicate to the public whether there were successful requests.

Section 40 – Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026: CMS has made the following changes and clarifications to policies detailed in section 40 of the initial memorandum:

- Manufacturer Negotiation Agreement: CMS revised section 40.1 to establish a process for a Primary Manufacturer that is unwilling to enter into an Agreement for the Negotiation Program to expedite its termination from the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program. The revised guidance also specifies that a Primary Manufacturer may terminate its Agreement with CMS at any time, provided the conditions for termination are met, as described in section 40.6 of this revised guidance.
- Data Submission, Confidentiality, and Data Use Provisions: CMS revised section 40.2.2 of the guidance to state that CMS will not publicly discuss ongoing negotiations prior to the release of the explanation of the maximum fair price (MFP) unless a Primary Manufacturer publicly discloses information regarding the negotiation process. Primary Manufacturers may choose to publicly disclose information regarding ongoing negotiations at its discretion. In addition, CMS will treat as proprietary certain data submitted by a Primary Manufacturer of a selected drug in accordance with sections 1194(e)(1) and 1194(e)(2) of the Act, but if a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary. CMS removed the data destruction requirements under the confidentiality policy pertaining to Primary Manufacturers in section 40.2.2 of this revised guidance. Section 40.2.3 of the revised guidance also provides that CMS will provide the Primary Manufacturer an opportunity for corrective action in the event a submission is incomplete or inaccurate.
- Public Explanation of MFP: CMS will publish a public explanation of the MFP for initial price applicability year 2026 for each selected drug by March 1, 2025 that will include a narrative explanation of the negotiation process, the agreed-upon MFP, and redacted

information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable.

- Use of Medicare Transaction Facilitator (MTF): CMS clarified in section 40.4 of this revised guidance that it intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to help effectuate access to the MFP through a retrospective refund model. CMS is also exploring allowing the use of a standardized refund amount from the manufacturers to the pharmacies under a retrospective refund model and confirms it will require the use of a 14-day prompt pay standard for the refund from manufacturers to pharmacies and other dispensing entities to reimburse dispensing entities for passing through the MFP.
- Suggestion of Error: CMS clarified in section 40.5 of this revised guidance that if a Primary Manufacturer in good faith believes that CMS has made an error in the calculation of the ceiling or the computation of MFP across dosage forms and strengths, the Primary Manufacturer can submit a suggestion of error. CMS will respond to suggested errors within 30 days.
- Manufacturer Ownership Transfer of Selected Drugs: CMS clarified in section 40.7 of this revised guidance the Primary Manufacturer's ongoing responsibilities if the Primary Manufacturer of a selected drug transfers ownership of one or more New Drug Application(s) (NDA) / Biologics License Application(s) (BLA) of the selected drug to another entity, unless and until the Primary Manufacturer transfers all the NDAs / BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer as evidenced by a novation that meets certain criteria.

Section 50 – Negotiation Factors: In the revised guidance, CMS reaffirmed that it will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. CMS also clarified that, for initial price applicability year 2026, it will review cost-effectiveness measures and studies that use such measures to determine whether the measure used may be considered in accordance with section 1194(e)(2) of the Act. However, while such measures may be considered, they will not be used to adjust the initial offer if the measure does not provide relevant information or is not permitted in accordance with section 1194(e)(2) of the Act and section 1182(e) of the Act. CMS has also noted that outcomes such as changes to productivity, independence, and quality of life will be considered when these outcomes correspond with a direct impact on the individuals taking the selected drug or therapeutic alternative(s) and are permitted by section 1194(e)(2) of the Act.

Section 60 – Negotiation Process: CMS has revised the guidance to provide additional detail about how CMS will use the days' supply field in PDE data to calculate a 30-day equivalent supply using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) when calculating the MFP ceiling (described in section 60.2 of this revised guidance) and using the Wholesale Acquisition Cost (WAC) ratio to apply the MFP across dosage forms and strengths (described in section 60.5 of this revised guidance). As described in section 60.3.2 of this revised guidance, when comparing prices of therapeutic alternatives for purposes of informing a starting price for the initial offer, CMS may use an alternative methodology for calculating a 30-day equivalent

supply when appropriate. In addition, the following revisions were made in this section of the guidance:

- Limitations on Offer Amount: CMS has revised section 60.2 of this revised guidance to use the single ceiling per 30-day equivalent supply across all dosage forms and strengths of the selected drug. CMS has also clarified that the time period for determining whether a selected drug is an extended- or long-monopoly drug runs from NDA approval to the start of the applicable initial price applicability year and clarified that PDE units will be used when averaging non-Federal average manufacturer price ("non-FAMP") across 11-digit National Drug Codes (NDC-11s).
- Unmet Medical Need: In section 60.3.3.1, CMS has revised the definition of unmet medical need to further align with FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics."[1]
- Addition of Manufacturer and Patient-Focused Meetings: To facilitate communication with manufacturers, CMS has described in section 60.4 that a CMS-manufacturer meeting will be added to the overall MFP negotiation process that would occur in Fall 2023 after the October 2, 2023 manufacturer data submissions, so that the manufacturer has an opportunity to present the data elements submission and share new information on the section 1194(e)(2) factors, if applicable, with CMS. In addition, CMS will be holding patient-focused listening sessions in Fall 2023 after the October 2, 2023 deadline for patients and other interested parties to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs.
- Negotiation Process: CMS revised section 60.4.3 to clarify that CMS will respond in writing no later than 30 days after receipt of a manufacturer's counteroffer regardless of whether CMS accepts or rejects the counteroffer. CMS has clarified that, to effectuate any MFP agreed upon by CMS and the Primary Manufacturer, both CMS and the Primary Manufacturer must sign and execute an Addendum to the Agreement. CMS also clarified in section 60.4.4 of the revised guidance that if an agreement on an MFP is not reached by the statutory end of the negotiation period, the Primary Manufacturer will enter a period during which an excise tax potentially may be assessed. The Primary Manufacturer can end this period by agreeing to an MFP or sending a notice terminating all of its applicable agreements under the Medicare and Medicaid programs and establishing that none of the Primary Manufacturer's drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act.
- Publication of MFPs for Selected Drugs: CMS clarified in section 60.6 of the revised guidance that CMS will publish the following on the CMS website by September 1, 2024 for all initial price applicability year 2026 selected drugs where an MFP was agreed upon: the selected drug, the initial price applicability year, and the MFP pricing file (which would be updated annually to show the inflation-adjusted MFP for a selected drug). CMS will strive to publish the explanation of the MFP earlier than March 1, 2025, if feasible.
- Manufacturer Delay in Negotiation Process: CMS has clarified in section 60.8 of the revised guidance that, if a Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, CMS will continue to engage in the negotiation process, as described in section 60.4. If delays occur such that the MFP is established after the end of the

[1] FDA Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics, May 2014. See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics.

negotiation period, CMS will follow timelines consistent with this revised guidance and take the time to complete the negotiation process as described.

Section 70 – Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect: In accordance with the policy clarification in section 30, CMS clarified that, in addition to monitoring PDE data for a selected drug, CMS will use AMP data reported by manufacturers to determine whether bona fide marketing is occurring when the agency undertakes the process of deselecting a selected drug and monitoring for the continued bona fide marketing of a generic drug or biosimilar. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of the generic drug or biosimilar biological product is engaging in bona fide marketing of that drug or product.

In addition, the revised guidance clarifies that status as a selected drug is unaffected by whether the Primary Manufacturer effectuates or terminates the Agreement to participate in the Negotiation Program or divests of the selected drug.

Section 80 – MFP-Eligible Individuals: CMS clarified in section 80 of this revised guidance that for initial price applicability year 2026, an MFP for a selected drug must be provided to a Medicare beneficiary who uses their Part D plan (including a Medicare Advantage Prescription Drug (MA-PD) plan under Medicare Part C or an Employer Group Waiver Plan) if Part D coverage is provided under such plan for such selected drug. The MFP is not required to be made available to a Medicare beneficiary who uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash. For initial price applicability year 2026, CMS does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to MFP eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan.

Section 90 – Manufacturer Compliance and Oversight: CMS made revisions to note that, while the statute clearly requires that the manufacturers of selected drugs are responsible for providing access of the MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers, CMS intends to engage with an MTF to facilitate the exchange of data between supply chain entities to verify eligibility of MFP-eligible individuals such that the MFP can be effectively passed through by the manufacturer to pharmacies, mail order services, and other dispensers. CMS also intends to explore options to facilitate retrospective payment exchange between interested parties to help effectuate access to the MFP.

Consistent with the changes and clarifications noted in sections 30 and 70 of this summary, CMS has also reaffirmed in section 90.4 of this revised guidance that it intends to monitor whether the manufacturer of a generic drug or biosimilar for the selected drug is engaging in "bona fide marketing" of the product by reviewing both PDE data and AMP data. CMS has also clarified that use of these data is not exhaustive, and all data and other information will be reviewed in totality in monitoring if manufacturers of these applicable generic drugs and biosimilars continue to engage in bona fide marketing.

Section 100 – Civil Monetary Penalties (CMPs): In the revised guidance, CMS has provided additional details on the CMP Notification that will be sent to the Primary Manufacturer, an opportunity for corrective action in applicable circumstances, additional details on CMP calculations, and information regarding the payment and appeals processes. CMS will provide an opportunity for corrective action prior to imposing CMPs in some circumstances, providing, for example, a Notice of Potential Noncompliance that includes an opportunity for the Primary Manufacturer to correct or mitigate noncompliance in applicable situations. CMS also revised the guidance to adopt a definition for "knowingly" that is consistent with language used by the Office of the Inspector General in administration of CMPs at 42 C.F.R. § 1003.110 such that "knowingly" means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required. CMS has also removed the "knowingly" requirement as related to the submission of false information under the Manufacturer Agreement.

Section 110 – Part D Formulary Inclusion of Selected Drugs: The revised guidance has clarified that the statute requires Part D plans to include on their formularies all dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect and has established the agency's expectations for how this requirement will be met for initial price applicability year 2026.

Section 120 – Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs: In the revised guidance, CMS has reaffirmed that selected drugs will also be subject to the Part D drug inflation rebate, but clarified that the MFP for a selected drug is not included in the AMP for the selected drug and thus will not affect the Part D inflation rebate calculation (see section 1927(k)(1)(B)(i)(VI)).

Appendix C – Definitions for Purposes of Collecting Manufacturer-Specific Data: After consideration of the comments on this guidance and the Negotiation Data Elements Information Collection Request (ICR) (CMS-10847 / OMB 0938-NEW), CMS has revised certain definitions in Appendix C. For example, CMS has revised the definition of non-FAMP in Appendix C to clarify that any restatements of the non-FAMP made in any applicable manufacturer non-FAMP submissions to the Department of Veterans Affairs must be reflected in the non-FAMP submitted to CMS as part of the section 1194(e)(1) data submission. CMS has consolidated several research and development (R&D) cost categories in Appendix C and has revised the R&D-related definitions by, for example, requiring reporting of acquisition costs as part of R&D rather than market data and revenue and sales volume data. CMS has also revised Appendix C to clarify that CMS will consider both a Primary Manufacturer's global and U.S. revenue when determining whether to adjust the preliminary price based on manufacturer-submitted data. In addition, CMS has revised the definition related to patents and exclusivities to provide clarification about the types of patents and patent applications that CMS considers to be "related to" the selected drug.

CMS removed certain definitions in Appendix C that are no longer needed due to deletions and revisions to information requested in the 30-day public notice for comment on the Negotiation Data Elements Information Collection Request, including 340B ceiling price, 340B prime vendor program price, manufacturer average net unit price to Part D plans, and quarterly total U.S. unit

volume. CMS revised the definition of unmet medical need and clarified when CMS will consider caregiver perspectives and outcomes such as changes to productivity, independence, and quality of life.

CMS directs interested parties to the 30-day public notice for comment on the Negotiation Data Elements ICR for revisions to ICR instructions and questions that are out of scope for this revised guidance.

C. Summary of Public Comments on the Initial Medicare Drug Price Negotiation Program Memorandum and CMS' Responses

CMS Statutory Authority to Issue Program Instruction and to Issue Section 30 of the Initial Memorandum as Final

Comment: Many commenters stated that CMS should use notice-and-comment rulemaking procedures to implement sections of the IRA. Specifically, a few commenters suggested that by issuing policy through program instruction, CMS violated the Administrative Procedure Act (APA) and the Medicare statute, which require use of notice procedures in certain circumstances and 60 days for comment. Relatedly, a few commenters stated that CMS violated the Due Process Clause of the U.S. Constitution by releasing section 30 of the initial memorandum as final without soliciting comments. Commenters asserted that in relying on the strict statutory deadlines for implementing the Negotiation Program as the rationale for issuing section 30 of the initial memorandum as final, CMS has not shown "good cause" to issue section 30 as final. In addition, a couple of commenters indicated that by issuing section 30 as final, CMS exceeded the scope of what Congress permitted in statute and engaged in *ultra vires* conduct.[2] Some commenters stated that it was improper for CMS to establish substantive obligations without providing notice and opportunity for comment, with one of these commenters further stating that such obligations are invalid and unenforceable because the guidance did not go through rulemaking procedures. A couple of commenters also wrote that the fact that CMS published the initial memorandum seven months after the IRA was enacted does not exempt it from providing opportunities for comment. Several commenters specifically requested that CMS use notice-and-comment rulemaking to codify the negotiation process for initial price applicability years 2027 and beyond. Other commenters recommended that CMS finalize the guidance well in advance of the selected drug publication date for initial price applicability year 2026 to provide interested parties with adequate time to review this revised guidance and conform their actions accordingly.

Response: Sections 11001(c) and 11002(c) of the IRA state that CMS "shall implement" the Negotiation Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." Thus, the initial memorandum is not subject to the notice-and-comment requirements of the APA or the Medicare statute. The terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. The statutory directive in sections 11001(c) and 11002(c) thus specifies that CMS shall follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under the APA or the

[2] *Ultra vires* means "beyond the powers," and is used to describe actions taken by governmental bodies that exceed the scope of power given to them by law.

Medicare statute. Congress underscored this directive by placing the Negotiation Program in the newly-enacted Part E of Title XI of the Social Security Act.

Even if the notice-and-comment procedures of the APA and the Medicare statute were applicable, the use of those procedures would be impracticable, unnecessary, and contrary to the public interest, and CMS thus had good cause to depart from those procedures. CMS solicited public comment on many key aspects of the initial memorandum, and also concluded, as stated in the initial memorandum, that in light of the complexity of the actions that must be undertaken in advance of the statutorily-mandated publication of the selected drug list by September 1, 2023, there was good cause to issue parts of the initial memorandum as final, including section 30, without soliciting public comment and without a delayed effective date. CMS reiterates this good-cause justification in this final guidance. CMS also has good cause to issue this revised guidance as final in advance of the statutory September 1, 2023, publication date of the selected drug list for initial price applicability year 2026. CMS agrees with the commenters who encouraged CMS to finalize the guidance well in advance of September 1, 2023 in order to allow interested parties advanced notice of the final policies for the Negotiation Program for initial price applicability year 2026. In particular, manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture will be included on the selected drug list for initial price applicability year 2026. For example, manufacturers may need to engage in internal discussions regarding whether the manufacturers would choose to participate in the Negotiation Program if their drug is included on the selected drug list published on September 1, 2023, review the template Medicare Drug Price Negotiation Program Agreement and guidance to understand Negotiation Program requirements for participating manufacturers in advance of the statutory deadline of October 1, 2023, for entering agreements, and gather information for potential submission to CMS by the statutory deadline of October 2, 2023. In addition, for the reasons explained below, the deadline for a biosimilar manufacturer to submit a delay request under section 1192(f) of the Act was May 22, 2023. CMS could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far in advance of these deadlines to allow them adequate time to complete their preparations for potential participation in the Negotiation Program.

Although section 30 was issued as final in the initial memorandum due to these timing constraints, CMS received many comments on section 30. In this guidance, CMS summarizes and responds to those comments, and CMS revised section 30 to help clarify, as needed, the policies it will follow to implement the selection of drugs for initial price applicability year 2026. CMS will continue to consider these comments as it develops guidance and rulemaking for future years of the Negotiation Program.

CMS also disagrees that the use of program guidance to implement the Negotiation Program for initial price applicability year 2026 or the issuance of section 30 as final violates the Due Process Clause of the U.S. Constitution. To the contrary, the reason CMS has undertaken efforts to finalize this guidance well before September 1, 2023, is to ensure that interested parties have advance notice about the procedures CMS will use to implement the Negotiation Program in accordance with the statute. The statute expressly directs CMS to use program guidance rather than notice-and-comment rulemaking to implement the Negotiation Program for 2026, 2027, and 2028, and, even so, through the publication of the initial memorandum, CMS ensured that

interested parties were given notice of and an opportunity to comment on many key aspects of the procedures CMS intends to follow in advance of any selection or negotiation for initial price applicability year 2026. And as explained, although CMS did not solicit comment on section 30, it received many comments on that section and revised to clarify the section in light of those comments.

Further, since enactment of the IRA in August 2022 CMS has engaged with interested parties through various platforms. On January 11, 2023, CMS issued a memorandum outlining how CMS will approach implementation of the Negotiation Program for initial price applicability year 2026, including engagement with the public; program guidance; information collection requests; and a timeline outlining key dates.[3] CMS considered the feedback it received through this engagement in the development of the initial memorandum for the Negotiation Program. Following the issuance of the initial memorandum in March 2023, CMS continues to engage with interested parties, with the intention to engage interested parties throughout implementation of the Negotiation Program.

Between September 2022 and March 2023, CMS accepted 104 meetings with interested parties representing the views of consumer and patient organizations, health care providers, health plans, PBMs, pharmaceutical and biotechnology manufacturers, pharmacies, researchers and academic experts, and wholesalers. In these meetings, CMS leadership and staff received feedback on implementation of the Negotiation Program ranging from policy concerns, questions requiring clarification, and recommendations on policy or operations. CMS also received 129 written materials totaling more than 1,100 pages submitted by pharmaceutical and biotechnology manufacturers and their trade associations, researchers and academic experts, consumer and patient organizations, and health plans and their trade associations, among other interested parties, before publishing the initial memorandum. Based on CMS' tracking of meeting agendas and materials provided, interested parties commonly provided feedback on key Negotiation Program topics including how to identify qualifying single source drugs for negotiation, how to apply the Orphan Drug Exclusion, how to operationalize requests by a biosimilar sponsor to delay selection and negotiation of a biological product that is a reference product for biosimilar market entry, and how to effectuate the MFP. Additionally, CMS leadership participated in 22 speaking engagements on IRA implementation hosted by interested parties. In addition to meetings with interested parties on specific issues of importance to the individual company or organization, CMS has held monthly one-hour calls open to all pharmaceutical and biotechnology manufacturers since December 2022. During these monthly calls, CMS staff provide an overview of recent IRA activities and take questions from manufacturer participants. In addition, in Fall of 2022, CMS established an IRA webpage for all program policies and updates and created an IRA mailbox (IRARebateandNegotiation@cms.hhs.gov) to receive queries from the public related to implementation of the Part B and Part D Inflation Rebate Program and the Negotiation Program. For example, CMS has received queries through the IRA mailbox from interested parties on how to ensure beneficiaries have access to the MFP through their Part D plan.

[3] CMS memorandum *Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026.* Accessible at https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf.

Through external meetings with interested parties, monthly IRA calls with pharmaceutical and biotechnology manufacturers, and the IRA mailbox, interested parties have had multiple touchpoints with CMS. Therefore, CMS disagrees that it has not provided opportunity for interested parties to engage with CMS on policies that may impact their business operations and patients. CMS remains committed to ongoing engagement efforts with interested parties and plans to meet with the Primary Manufacturer of each selected drug as well as hosting patient-focused listening sessions on the selected drugs in Fall 2023, as described in section 60.4 of this revised guidance.

Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2026 (Section 30.1)

Comment: CMS received many comments on its reading of the statute to aggregate all dosage forms and strengths of a drug with the same active moiety and the same holder of the NDA or of a biological product with the same active ingredient and the same holder of the BLA, for the purposes of identifying potential qualifying single source drugs. Some commenters stated that this approach is consistent with the clear statutory instruction to aggregate across dosage forms and strengths. A couple of commenters stated that this policy is critical to prevent gaming. In their view, this reading of the statute will prevent pharmaceutical manufacturers from engaging in "product hopping," attempting to shift use of their products away from those with an MFP to those without an MFP, based solely on modest or minor modifications, a practice which increases revenue for pharmaceutical companies. Other commenters asserted that this approach is not supported by the statute and that the statute defines a qualifying single source drug in reference to a distinct NDA or BLA.

Response: Section 1192(d)(3)(B) of the Act directs CMS to "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug" for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures "to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug." The aggregation rules under sections 1192(d)(3)(B) and 1196(a)(2) are clear, and are designed to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries as intended by the law. Because different dosage forms and strengths, as well as different formulations, of an active moiety / active ingredient can be approved or licensed under multiple NDAs or BLAs, the suggestion from commenters to define a qualifying single source drug in reference to a distinct NDA or BLA is inconsistent with sections 1192(d)(3)(B) and 1196(a)(2) of the Act. Contrary to the views of some commenters, section 1192(d)(3)(B) refers to the aggregation of data "across dosage forms and strengths of the drug, including new formulations of the drug," thereby necessarily establishing that the statutory negotiation procedures apply more broadly than to a distinct NDA or BLA. Unlike the views offered by some commenters, CMS' understanding of the statutory language gives full effect to all relevant provisions of the statute, including sections 1192(e), 1192(d)(3)(B), and 1196(a)(2) of the Act; CMS is applying an interpretation of the statute that follows the statutory criteria for the identification of a qualifying single source drug under section 1192(e) of the Act and,

consistent with sections 1192(d)(3)(B) and 1196(a)(2) of the Act, gives effect to the statutory policy that a drug that may be selected for negotiation includes multiple dosage forms and strengths and formulations of that drug.

CMS agrees with commenters that complying with the statutory requirement to identify a qualifying single source drug using data that is aggregated across different dosage forms and strengths, as described in the initial memorandum, will decrease incentives for pharmaceutical manufacturers to engage in "product hopping." This statutory requirement ensures that products by the same sponsor with the same active moiety / active ingredient are subject to the same processes under the Negotiation Program, and that a manufacturer is therefore limited in its ability to shift use of its products away from those with an MFP to those without an MFP, based on modest or minor modifications. Reducing "product hopping" is consistent with the purpose of the statute, which is to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries. For the above reasons, in this revised guidance, CMS maintains the approach described in the initial memorandum for identifying potential qualifying single source drugs.

Comment: Some commenters raised questions about how CMS will treat products that have different formulations or routes of administration within the same qualifying single source drug, given the policy to define a qualifying single source drug based on active moiety or active ingredient. Some commenters expressed concerns that aggregation will limit pharmaceutical innovation, including innovation for rare diseases and conditions, and commenters urged CMS to consider the patient perspective on whether new formulations demonstrate an improvement to patient care. In contrast, one commenter was concerned that aggregating products with different indications and/or routes of administration into the same qualifying single source drug could be problematic because one product with different indications and/or routes of administration from the other products within a potential qualifying single source drug could have a generic or biosimilar competitor that would disqualify all products from the Negotiation Program.

Response: CMS thanks these commenters for their input. CMS is committed to recognizing the clinical benefit of products, including products with different formulations or routes of administration from other products that are aggregated as part of the same qualifying single source drug, and directs readers to section 60.3.3 of this revised guidance, which details CMS' approach to adjusting the starting point for an initial offer based on clinical benefit.

CMS appreciates the concern raised that a generic or biosimilar competitor for one product within a potential qualifying single source drug will disqualify all products within that potential qualifying single source drug from the Negotiation Program. However, as explained above, the statute directs CMS to aggregate across dosage forms and strengths of the drug, and CMS must apply that requirement faithfully not only for purposes of identifying the qualifying single source drug, but also for purposes of disqualifying products with generic or biosimilar competition that satisfies the relevant statutory criteria.

CMS is committed to ensuring that the statutory criteria are satisfied for any such disqualification, including the requirement that a generic or biosimilar be "marketed." This is particularly important given that a drug or biological product will not be considered a qualifying

single source drug for initial price applicability year 2026 if such competition is determined to exist at the time of drug selection; if such determination occurs after drug selection, it will cause a selected drug (1) to be no longer subject to the negotiation process or (2) to cease to be a selected drug, depending on the timing of such determination. CMS directs readers to section 90.4 of this revised guidance, which details how CMS will monitor whether a generic drug or biosimilar competitor is engaging in bona fide marketing such that a potential qualifying single source drug is disqualified from participation in the Negotiation Program.

Comment: Many commenters asserted that the distinct time periods for when a drug versus biological product will be eligible for negotiation are arbitrary and that CMS should implement the Negotiation Program so that, for any drug or biological product to qualify as a qualifying single source drug, at least 11 years must have elapsed since the drug or biological product was approved or licensed, respectively.

Response: Section 1192(e)(1)(A)(ii) of the Act states that for a drug product to be considered a qualifying single source drug, at least 7 years must have elapsed since the drug product was approved by the FDA.[4] Section 1192(e)(1)(B)(ii) of the Act states that for a biological product to be considered a qualifying single source drug, at least 11 years must have elapsed since the biological product was licensed by the FDA.[5] CMS is implementing the program in accordance with these statutory requirements.

Comment: A couple of commenters expressed support for CMS' reading of the statute in the initial memorandum on fixed combination drugs with two or more active moieties / active ingredients, which treats the distinct combination of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs. One commenter raised a concern that this reading, while sensible in some cases, creates a gaming opportunity for manufacturers to seek approval of fixed combination drugs with one active moiety / active ingredient in common and market them in a way that could influence volume for each fixed combination drug in an effort to avoid selection. For example, a sponsor might market a fixed combination drug that contains active moiety / active ingredient X and Y and a fixed combination drug that contains active moiety / active ingredient X and Z. The commenter encouraged CMS to aggregate sales for fixed combination drugs with other dosage forms containing the newest active moiety / active ingredient if the products are made by the same manufacturer.

Response: CMS appreciates commenters' support for its understanding of the statutory language and acknowledges the concern outlined by one commenter. CMS believes that a fixed combination drug is distinct in its composition from the individual active moieties / active ingredients and in this revised guidance maintains its approach on fixed combination drugs,

[4] For drug products, to determine the date of approval for a potential qualifying single source drug with more than one FDA application number, section 30.1 of this revised guidance specifies that CMS will use the earliest date of approval of the initial FDA application number assigned to an NDA for the active moiety for which the manufacturer is the holder of the NDA.

[5] For biological products, to determine the date of approval for a potential qualifying single source drug with more than one FDA application number, section 30.1 of this revised guidance specifies that CMS will use the earliest date of licensure of the initial FDA application number assigned to a BLA for the active ingredient for which the manufacturer is the holder of the BLA.

which treats the distinct combination of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs.

Orphan Drug Exclusion from Qualifying Single Source Drugs (Section 30.1.1)

Comment: Many commenters asked CMS to clarify that the 7- or 11-year periods prior to eligibility as a qualifying single source drug would begin on the date the Orphan Drug Exclusion ceases to apply to a drug or biological product. That is, a drug or biological product could not become a qualifying single source drug until 7 or 11 years had passed between the date on which the drug or biological product, respectively, loses eligibility for the Orphan Drug Exclusion and the selected drug publication date.

Response: CMS does not have the statutory authority to change the starting date from which qualifying single source drug status is determined. Sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act require CMS to use the date of the approval or licensure of the drug or biological product to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Act. CMS has added language to section 30.1.1 of this revised guidance to clarify the timing that CMS will use to identify qualifying single source drugs.

Comment: Many commenters asserted that drugs or biological products with multiple orphan designations (for multiple rare diseases or conditions) that are approved only for indications within the scope of a single rare disease or condition should qualify for the Orphan Drug Exclusion. A few commenters remarked that designating a drug under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for a rare disease is done very early in the drug development process and is important to unlocking Orphan Drug Act incentives. These commenters expressed concern that the current Orphan Drug Exclusion policy in the Negotiation Program will stymie innovation for drugs or biological products and discourage sponsors from seeking designations for more than one rare disease or condition.

Response: CMS thanks these commenters for their feedback. Section 1192(e)(3)(A) of the Act describes a drug that qualifies for the Orphan Drug Exclusion as a "drug that is designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and for which the only approved indication (or indications) is for such disease or condition." CMS therefore does not have the statutory authority to exclude a drug under the Orphan Drug Exclusion that has designations for multiple rare diseases or conditions, even if the drug has been approved only for indication(s) within a single rare disease or condition. CMS has added a clarification about designations for multiple rare diseases or conditions to section 30.1.1 of this revised guidance, which addresses how CMS will implement this exclusion.

Comment: A couple of commenters urged CMS to interpret the term "rare disease or condition" with sufficient breadth to capture designations and approved indications for different mutations or subtypes of one disease. Commenters noted that this interpretation would allow a drug or biological product to seek designations and approvals for sub-conditions within the same rare

disease or condition and remain eligible for the Orphan Drug Exclusion and would preserve incentives for drug development across sub-conditions.

Response: CMS will follow the statutory directive in section 1192(e)(3)(A) of the Act to consider orphan designations and approvals within the scope of the same rare disease or condition. As clarified in section 30.1.1 of this revised guidance, CMS will consult with the FDA as needed to determine whether a drug is designated under section 526 of the FD&C Act for, or has approved indications for, one or more rare diseases or conditions, as part of determining whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the Orphan Drug Exclusion.

Comment: Commenters offered contrasting perspectives on whether CMS should consider orphan designations that have been withdrawn when evaluating a drug or biological product for the Orphan Drug Exclusion. Some commenters asserted that CMS should not consider withdrawn designations. In contrast, one commenter recommended that CMS should consider withdrawn designations because a manufacturer could withdraw a designation that is not yet FDA-approved so that a drug or biological product could qualify for the Orphan Drug Exclusion.

Response: CMS appreciates this feedback. CMS understands that a drug or biological product may be designated for a rare disease or condition early in the drug development process, and that designation might not always result in FDA-approved indications that fall within the scope of that designation, and that a manufacturer may choose to withdraw the designation. Similarly, there may be situations where, for example, a manufacturer decides to request that FDA withdraw approval of an indication. In accordance with section 1192(e)(3)(A) of the Act, only designations and approvals active at the time of identifying qualifying single source drugs will be considered for purposes of determining a drug's eligibility for the Orphan Drug Exclusion to best reflect the status of the drug at the time it is evaluated for qualifying single source drug eligibility. As such, CMS has clarified in section 30.1.1 of this revised guidance that it will not consider withdrawn orphan designations or withdrawn approvals when evaluating a drug for the Orphan Drug Exclusion.

Comment: A few commenters raised questions as to whether a potential qualifying single source drug will qualify for the Orphan Drug Exclusion if some but not all dosage forms and strengths of that potential qualifying single source drug meet the Orphan Drug Exclusion criteria. One commenter requested that, when a drug or biological product loses eligibility for the Orphan Drug Exclusion, CMS carve out the original approval(s) that qualified for the Orphan Drug Exclusion from the resulting qualifying single source drug. Another commenter requested that potential qualifying single source drugs that qualify for the Orphan Drug Exclusion must qualify across all dosage forms and strengths. An additional commenter asked whether a fixed combination drug will qualify for the exclusion if only one of the two active moieties / active ingredients qualifies for the Orphan Drug Exclusion.

Response: The initial memorandum states that, in order to qualify for the Orphan Drug Exclusion, "all dosage forms and strengths and different formulations of the qualifying single source drug described in section 30.1 of this memorandum must meet the criteria for exclusion." In this revised guidance, CMS maintains this requirement. Because section 1192(e)(3)(A) of the

Act is an exclusion from the definition of qualifying single source drug under section 1192(e)(1) of the Act, CMS must consider whether the drug, including all products that constitute the potential qualifying single source drug, meets the statutory criteria for the Orphan Drug Exclusion.

Comment: A few commenters expressed concern that the FDA Orphan Drug Product designation database and the FDA approvals database will not allow CMS to identify whether an indication falls within an orphan designation. To alleviate this concern, commenters recommended that CMS consult with FDA and consider written communications between FDA and the manufacturer during the review and approval process. Commenters also suggested that CMS establish a pathway for manufacturers and other interested parties to demonstrate that an indication falls within an orphan drug designation.

Response: CMS appreciates these comments. CMS believes that consulting the FDA Orphan Drug Product designation database and approvals on the FDA website, in addition to consultation with FDA as needed, will allow CMS to successfully implement the Orphan Drug Exclusion. CMS will monitor this approach to ensure that it accurately operationalizes the Orphan Drug Exclusion.

Comment: A few commenters requested that CMS support the development of diagnosis codes for rare diseases and disorders; support early dialogue between payers and rare disease manufacturers; and create new payment and service delivery models with the Center for Medicare and Medicaid Innovation (CMMI) that bolster innovation in the treatment of rare diseases or conditions.

Response: CMS noted in the initial memorandum that CMS is considering whether there are additional actions that CMS might take in its implementation of the Negotiation Program to support orphan drug development, and CMS directs readers to the discussion in section 60.3.3 of how it will consider unmet medical need and the impact of a selected drug on specific populations when developing the initial offer. CMS notes, however, that these specific requests related to CMMI, diagnosis code development, and other payers' interactions with manufacturers are outside the scope of this revised guidance.

Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs (Section 30.1.2)

Comment: A few commenters provided feedback on CMS' description of how it will calculate the Low-Spend Medicare Drug Exclusion. One commenter supported the approach that CMS detailed in the initial memorandum. Another commenter recommended that CMS include rebates in the calculation of Total Expenditures under Part B and Part D for purposes of the Low-Spend Medicare Drug Exclusion. One commenter recommended that CMS exclude beneficiary cost sharing under Part B and net out Direct and Indirect Remuneration (DIR) under Part D when calculating total Part B and Part D expenditures for purposes of this exclusion.

Response: For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) of the Act as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3) of the Act). The term "gross covered prescription

drug costs" is also defined in the Part D regulations at 42 C.F.R. § 423.308. In the initial memorandum, CMS indicated that it had proposed to update this regulatory definition of gross covered prescription drug costs to eliminate any potential ambiguity in the regulation text and help to ensure there is a consistent understanding of the term for purposes of both the Part D program and the IRA. Since the initial memorandum was issued, CMS has issued a final rule adopting the proposed revisions to 42 C.F.R. § 423.308 (see Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Final Rule (0938-AU96), 88 Fed. Reg. 22,120, 22,259 (Apr. 12, 2023)).[6] CMS has updated this revised guidance to reflect the issuance of the final rule.

Using PDE data combined with Part B claims data, inclusive of beneficiary cost sharing, to calculate combined Total Expenditures under Part D and Part B will allow CMS to implement the Low-Spend Medicare Drug Exclusion in a manner that aligns with the statute and regulatory policy. CMS will use Part B claims data that are inclusive of beneficiary cost sharing to determine Part B Total Expenditures to maintain consistency with the approach to determining "gross covered prescription drug costs" under Part D, which are defined in the statute and regulations as inclusive of Part D beneficiary cost sharing. CMS has clarified in section 30.1.2 of this revised guidance that, in accordance with section 1191(c)(5) of the Act, expenditures for a drug or biological product that are bundled or packaged into the payment for another service are excluded from the calculation of total allowed charges under Part B for purposes of determining Total Expenditures under Part B.

Comment: One commenter asked CMS to clarify that the 30-day additional period from June 1, 2023 to June 30, 2023 for Part D plan sponsors and Part B providers and suppliers to submit PDE and Part B claims data is a grace period.

Response: As described in section 30.1.2 of this revised guidance, the 30-day period from June 1, 2023 to June 30, 2023 provides time for data to be submitted. In identifying low-spend Medicare drugs for initial price applicability year 2026, CMS will only consider PDE data and Part B claims with dates of service that occur during the 12-month period beginning June 1, 2022, and ending May 31, 2023.

Plasma-Derived Product Exclusion from Qualifying Single Source Drugs (Section 30.1.3)

Comment: Some commenters asked CMS to provide further clarification on which products will be considered plasma-derived for the purpose of the Plasma-Derived Product Exclusion. A couple of commenters asserted that cellular or gene therapies should not be subject to the exclusion. A couple of commenters requested a more holistic approach to identifying plasma-derived products, such as through consultation with FDA and other interested parties.

Response: CMS continues to believe that referring to product information available on the FDA Approved Blood Products website[7] and the FDA Online Label Repository[8] is the best way to

[6] Accessible at: https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.
[7] See: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[8] See: https://labels.fda.gov/.

identify plasma-derived products for the purpose of implementing the Plasma-Derived Product Exclusion in a consistent manner. CMS agrees that there may be specific products where additional insights from FDA would be beneficial, and as noted in section 30.1.3, CMS will also consult with FDA as needed to implement this exclusion.

CMS confirms that cellular and gene therapies are not categorically ineligible for the Plasma-Derived Product Exclusion described in section 1192(e)(3)(C) of the Act, which applies the exclusion to biological products derived from human whole blood or plasma. As described by FDA, cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications. As further described by FDA, human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use.[9] Cellular and gene therapies will be assessed using the same standards as other biological products to determine whether they qualify for the Plasma-Derived Product Exclusion.

Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2026 (Section 30.2)

Comment: One commenter asked CMS to clarify whether rebates will be incorporated into the calculations used to rank the 50 negotiation-eligible drugs.

Response: In identifying and ranking the negotiation-eligible drugs for initial price applicability year 2026, CMS will use Total Expenditures under Part D, which are defined at section 1191(c)(5) of the Act as "total gross covered prescription drug costs," as defined in section 1860D-15(b)(3). Section 1860D–15(b)(3) of the Act defines "gross covered prescription drug costs" in relevant part as "the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible." The term is also defined in the Part D regulations at 42 C.F.R. § 423.308. As discussed in the Contract Year 2024 Final Rule (see 88 Fed. Reg. 22,120, 22,259 (Apr. 12, 2023)), costs directly related to the dispensing of covered Part D drugs are most logically calculated as the accumulated total of the negotiated prices that are used for purposes of determining payment to the pharmacy or other dispensing entity for covered Part D drugs. Consistent with this policy, CMS will calculate Total Expenditures under Part D for purposes of the Negotiation Program using PDE data and will not consider any rebates or other price concessions not reflected in the negotiated price of the drug on the PDE to identify and rank negotiation-eligible drugs.

[9] See: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products.

Exception for Small Biotech Drugs (Section 30.2.1)[10, 11]

Comment: A couple of commenters requested that CMS create a dispute resolution process so that a manufacturer that disagrees with CMS' determination of its eligibility for the Small Biotech Exception can dispute this determination. One commenter requested that CMS allow small biotech companies to provide additional data after the deadline to support their application for the exception before CMS makes a final determination.

Response: CMS thanks these commenters for their recommendations. CMS requests all information necessary to determine eligibility for the Small Biotech Exception in the Small Biotech Exception ICR Form. Additionally, because of the ambitious statutory deadlines for the Negotiation Program for initial price applicability year 2026, CMS will not accept incomplete or late requests for the Small Biotech Exception for initial price applicability year 2026, including additional data submitted by companies to support their application after the deadline, but before CMS makes a final determination. CMS also declines to create a dispute resolution process for the Small Biotech Exception.

Comment: A couple of commenters requested further detail on the Small Biotech Exception for initial price applicability years 2027 and 2028. Commenters recommended that CMS introduce a streamlined application for manufacturers that had previously received the exception, wherein such manufacturers would only have to attest that they have not been acquired by another entity in order to receive the exception again. One commenter requested clarity on whether manufacturers only have one chance to apply for the Small Biotech Exception or if a manufacturer may submit each year.

Response: This revised guidance establishes the policies CMS will use to implement the Negotiation Program for initial price applicability year 2026. A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years. CMS will share the submission process for the Small Biotech Exception for initial price applicability years 2027 and 2028 in future guidance and appreciates the feedback received from commenters.

Comment: One commenter asserted that, for the purpose of identifying drugs that qualify for the Small Biotech Exception for initial price applicability year 2026, CMS must consider whether

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[10] On January 24, 2023, CMS released the Small Biotech Exception ICR (CMS-10844 / OMB 0938-1443) to detail the specific data that CMS is requesting for purposes of implementing this exception. The comment period for the 60-day notice closed on March 27, 2023, and the comment period for the 30-day notice closed on May 24, 2023. Section 30.2.1 of this revised guidance reflects revisions that CMS made in response to feedback from interested parties on the Small Biotech ICR and section 30.2.1 of the initial memorandum. Here, CMS responds to comments on the discussion of the Small Biotech Exception in the initial memorandum that raised inquiries or recommendations not already addressed by revisions to the Small Biotech ICR. To view the Small Biotech ICR Form, a summary of changes made to the Small Biotech ICR in response to comments received during the 60-day and 30-day notice periods, as well as comments received on the Small Biotech ICR and CMS' responses to those comments, please see https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016.

[11] On June 2, 2023, CMS released the Small Biotech Exception functionality in CMS HPMS. To request the Small Biotech Exception for a qualifying single source drug for initial price applicability year 2026, manufacturers must submit a Small Biotech Exception request via HPMS by 11:59 p.m. PDT on July 3, 2023.

Total Expenditures for a qualifying single source drug meet the expenditure requirements under either Part B or Part D. If the qualifying single source drug meets the requirements with respect to either Part B or Part D Total Expenditures, then that qualifying single source drug would qualify for the Small Biotech Exception.

Response: CMS appreciates this recommendation but, for initial price applicability year 2026, sections 1191(a) and 1192(d) of the Act require CMS to evaluate whether a qualifying single source drug meets the criteria to be considered a negotiation-eligible drug, including with respect to the Small Biotech Exception, based on Total Expenditures under Part D only.

Comment: One commenter requested that CMS make the Small Biotech Exception permanent rather than exclude small biotech drug products for only the first three years of the Negotiation Program.

Response: The Small Biotech Exception, as required by section 1192(d)(2)(A) of the Act, applies only with respect to initial price applicability years 2026, 2027, and 2028. CMS does not have the authority to make the Small Biotech Exception permanent.

Although the Small Biotech Exception is limited to initial price applicability years 2026, 2027, and 2028, CMS notes that the temporary floor for small biotech drugs described in section 1194(d) applies to qualifying single source drugs described in section 1192(d)(2) with respect to initial price applicability years 2029 and 2030.

Comment: One commenter requested that CMS clarify which 2021 Total Expenditure data it will use to determine eligibility for the Small Biotech Exception.

Response: As described in section 30.2.1 of this revised guidance, CMS will use PDE data for dates of service during the 12-month period beginning January 1, 2021 and ending December 31, 2021 to determine eligibility for the Small Biotech Exception.

Selection of Drugs for Negotiation for Initial Price Applicability Year 2026 (Section 30.3)

Comment: A few commenters requested greater transparency into the process of selecting drugs for negotiation. A couple of commenters requested that CMS notify the manufacturer of a drug that will be selected for negotiation at least 30 days in advance of the selected drug list publication date. One commenter asked that CMS publish the calculations used to determine the list of selected drugs and establish a process for manufacturers to identify concerns in advance of the selected drug publication date. A couple of commenters suggested that CMS establish a pathway for interested parties to provide input into which negotiation-eligible drugs are included on the selected drug list.

Response: For initial price applicability year 2026, the statute requires that CMS publish the selected drug list no later than September 1, 2023. CMS believes that disclosing to manufacturers whether their drug is a selected drug before this date is operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by September 1, 2023 for

initial price applicability year 2026. For example, sections 1191(d)(3)(B) and 1192(d)(1)(A) of the Act require that CMS identify negotiation-eligible drugs for initial price applicability year 2026 using Total Expenditure data during the period beginning on June 1, 2022, and ending on May 31, 2023. As discussed in section 30 of this revised guidance, Total Expenditures under Part D will be calculated using PDE data for dates of service between June 1, 2022 and May 31, 2023. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service during this 12-month period that have been submitted to CMS by June 30, 2023. The complexity of the data analyses and quality checks that must then be performed on the data prior to September 1, 2023 forecloses the possibility of disclosing to manufacturers whether their drug is a selected drug prior to the statutory selected drug list publication date for initial price applicability year 2026.

Although CMS appreciates the request for a pathway for interested parties to provide input into the selected drug list for initial price applicability year 2026, section 1192(b)(1)(B) of the Act requires that CMS select the highest ranked drugs from the list of negotiation-eligible drugs using Total Expenditures under Part D. CMS is committed to engaging with interested parties throughout the implementation of the Negotiation Program. As detailed earlier in this guidance, CMS solicited input from interested parties throughout the development of the initial memorandum and this revised guidance. Further, CMS refers readers to sections 50.2 and 60.3.3 of this revised guidance, which detail CMS' approach to adjusting the starting point for the initial offer using evidence submitted by the public on therapeutic alternatives to the selected drug, in accordance with section 1194(e)(2) of the Act. CMS also refers readers to section 60.4 of this guidance, which describes how, in response to comments from interested parties, CMS is providing for additional engagement opportunities for interested parties—specifically, meetings with manufacturers and patient-focused listening sessions—after the October 2, 2023 deadline for submission of section 1194(e) data.

Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry) (Section 30.3.1)

Comment: One commenter expressed support for a stringent process for assuring that a Biosimilar Manufacturer and Reference Manufacturer cannot have entered into agreements that require or induce the Biosimilar Manufacturer to limit market share, as well as the process for assuring that there is a high likelihood that the Biosimilar will be marketed before September 1, 2025. The commenter urged CMS to apply similar levels of scrutiny to all areas of implementation where proof of competition is required, including the definition of a qualifying single source drug.

Response: CMS appreciates this commenter's perspective. Section 1192(f)(2)(D)(iv) of the Act excludes certain Biosimilar Manufacturers from the Biosimilar Delay if CMS determines that the Biosimilar Manufacturer is the same as the Reference Manufacturer, or that the Biosimilar Manufacturer has entered into any agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or that restricts the quantity (either directly or indirectly) of the Biosimilar that may be sold in the United States over a specified period of time. As described in section 90.4 of this revised guidance, CMS plans to monitor whether the manufacturer of a generic or biosimilar competitor of a potential qualifying

single source drug or selected drug is engaging in bona fide marketing when identifying qualifying single source drugs and selected drugs.

Comment: One commenter expressed concern that a Reference Manufacturer will not have transparency into whether a Reference Drug will be a selected drug because the Reference Manufacturer will not know whether a Biosimilar Manufacturer has submitted an Initial Delay Request to delay the inclusion of that Reference Manufacturer's Reference Drug on the selected drug list. The commenter recommended that CMS publish a list of Biosimilar Manufacturers submitting an Initial Delay Request and make CMS' determinations known publicly.

Response: CMS thanks this commenter for raising this issue. The submission of an Initial Delay Request does not guarantee that a Reference Drug would be a selected drug absent the Initial Delay Request, nor does it guarantee that the Initial Delay Request will be granted even if the Reference Drug would be a selected drug absent the Biosimilar Delay. CMS, therefore, will not publish a list of Biosimilar Manufacturers submitting an Initial Delay Request or CMS' determinations. However, as described in section 30.3.1.4 of this revised guidance, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request of CMS' determination regarding such request on or after September 1, 2023, but not later than September 30, 2023. CMS will also notify each Reference Manufacturer named in a successful Initial Delay Request and will identify the Reference Drug that would have been a selected drug, absent the successful Initial Delay Request. In recognition that the public has an interest in understanding the impact of the Biosimilar Delay, CMS is clarifying in this revised guidance that it will publish the number of Reference Drugs that would have been selected drugs for initial price applicability year 2026, absent successful Initial Delay Requests, as part of publishing the selected drug list by September 1, 2023.

Comment: Some commenters asserted that the information required from a Biosimilar Manufacturer to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025 is too narrow. A couple of commenters contended that section 1192(f)(1)(B)(ii)(I)(aa) of the Act directs CMS to consider all documents that a Biosimilar Manufacturer believes support a high likelihood determination. One commenter stated that the Act does not specify that the scenarios described in sections 1192(f)(3)(A) and (B) are the only scenarios under which a high likelihood determination can be made. The commenter noted that other documentation should therefore suffice to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

Response: CMS thanks these commenters for their feedback related to the high likelihood determination. Section 30.3.1.2 of this revised guidance aligns with the statutory language, which requires CMS to identify whether a Biosimilar has a high likelihood of being licensed and marketed within two years after the publication of the selected drug list. CMS believes the information detailed in section 30.3.1.2 will allow CMS to implement the high likelihood provision of the Biosimilar Delay in a manner that benefits the Medicare program by minimizing the likelihood of CMS approving a delay request for a Biosimilar that is not highly likely to become licensed and marketed within two years after the publication of the selected drug list. Further, CMS believes this approach will support robust biosimilar competition.

Comment: One commenter stated that the metrics proposed to assess the operational readiness of a Biosimilar Manufacturer are generally sensible, but filings with the Securities and Exchange Commission (SEC) on future revenues are often subject to significant caveats about uncertainty and changing market conditions. The commenter recommended that CMS consider a more concrete indicator of operational readiness but did not provide any examples.

Response: CMS believes that section 30.3.1.2 of the guidance aligns with the statutory language and that SEC filings, despite any potential uncertainties, represent a meaningful source of information about a manufacturer's plans to manufacture and market a drug. CMS also notes that, in determining whether a Biosimilar Manufacturer will be operationally ready to market the Biosimilar before September 1, 2025, CMS will also consider supporting documentation provided to CMS as part of the Initial Delay Request, such as the copy of the manufacturing schedule submitted to FDA, which as CMS has clarified in section 30.3.1.2 of this revised guidance, must be consistent with public-facing statements and demonstrative of readiness to meet revenue expectations. Further, operational readiness is only one component of the high likelihood determination. To meet the high likelihood threshold, the Initial Delay Request must also demonstrate that an application for licensure under section 351(k) of the Public Health Service Act ("PHS Act") for the Biosimilar has been accepted for review or approved by FDA, and that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025.

Comment: One commenter explained that, upon review of a BLA, FDA may issue a Complete Response letter identifying the deficiencies that preclude approval. The applicant will generally work to address the deficiencies and resubmit the section 351(k) BLA, and FDA will generally act on a resubmitted section 351(k) BLA within six months of receipt. The commenter recommended that CMS make clear that a section 351(k) BLA in Complete Response status remains eligible for the Special Rule Delay.

Response: CMS thanks this commenter for the recommended clarification. CMS has clarified in section 30.3.1.2 of the guidance that CMS will consider a section 351(k) application for licensure that has been accepted for review and has received a Complete Response letter to meet the section 1192(f)(3)(A) requirement that a section 351(k) BLA for the biosimilar biological product has been accepted for review by FDA.

Comment: One commenter recommended that CMS collaborate with FDA to identify key milestones that would indicate a high likelihood that a Biosimilar will be licensed and marketed before September 1, 2025.

Response: Both the initial memorandum and revised guidance incorporate technical assistance from FDA along with other federal agencies. To demonstrate there is a high likelihood that a Biosimilar will be licensed and marketed before September 1, 2025, an Initial Delay Request must demonstrate that the Biosimilar meets the high likelihood threshold described in section 30.3.1.2 of the revised guidance. This threshold requires that, for Initial Delay Requests submitted with respect to initial price applicability year 2026, the Biosimilar's application for licensure must be approved or accepted for review by FDA no later than August 15, 2023, and that the Initial Delay Request demonstrate clear and convincing evidence that the Biosimilar will

be marketed before September 1, 2025. The clear and convincing evidence criteria will be satisfied if the Initial Delay Request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. CMS will continue to consult with FDA as needed on its policies for implementing the Biosimilar Delay.

Comment: One commenter stated that the purpose of the manufacturing schedule submitted to FDA during FDA's review of a section 351(k) BLA – and to CMS under section 1192(f)(1)(B)(ii)(III)(aa) of the Act – is to facilitate an FDA inspection of the establishment that is manufacturing the biological product to confirm the establishment is in operation and manufacturing the proposed product. This manufacturing schedule, therefore, does not reflect any post-approval manufacturing dates. The commenter advised CMS to omit the reference to "consistent with the public-facing statements and any revenue expectations" in the revised guidance.

Response: CMS thanks this commenter for offering their perspective on the uses of the manufacturing schedule submitted to FDA during FDA's review of a section 351(k) BLA. CMS has included a clarification in section 30.3.1.2 of this revised guidance that the manufacturing schedule must be consistent with the manufacturer's public-facing statements and demonstrate readiness to meet revenue expectations, in recognition that the schedule does not reflect post-approval manufacturing dates.

Comment: A few commenters remarked that ongoing patent litigation may be irrelevant to a Biosimilar launch. A Biosimilar Manufacturer can carve out indications with active patents from the Biosimilar's labeling, or a Biosimilar can launch at risk. The commenters asserted that active litigation should, therefore, not prevent manufacturers from meeting the high likelihood threshold.

Response: CMS has clarified that an Initial Delay Request for initial price applicability year 2026 only has to meet one of the following criteria to satisfy the patent-related component of the high likelihood determination: (1) there are no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer. For example, if a Biosimilar Manufacturer has carved out a patent-protected indication or method of use from the Biosimilar's labeling, then such patents would not be considered to be "applicable to the Biosimilar." CMS reiterates that the above criteria reflect how CMS will determine if the Initial Delay Request clearly demonstrates that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025.

Comment: A few commenters requested that CMS clarify the specific circumstances under which CMS will find that an agreement between a Biosimilar Manufacturer and a Reference

Manufacturer would disqualify a Biosimilar Manufacturer from making an Initial Delay Request. The commenters noted that a signed legal agreement between the Reference Manufacturer and the Biosimilar Manufacturer permitting the Biosimilar Manufacturer to market the Biosimilar may serve as evidence that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed. At the same time, however, for a Biosimilar Manufacturer to meet the requirements for CMS to grant an Initial Delay Request, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or that directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

Response: CMS does not believe that the two agreement types that the commenters raise conflict since it is possible to have an agreement that permits commercialization without either directly or indirectly restricting volume or incentivizing the Biosimilar Manufacturer to submit an Initial Delay Request. CMS reiterates that, consistent with section 1192(f)(2)(D)(iv)(II) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that either requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or that directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

Comment: A few commenters expressed concern that the timeline for submitting Initial Delay Requests is unreasonably accelerated and will jeopardize the accuracy of the requests and create a barrier to biosimilar competition, as the timeline effectively eliminates the additional runway for a Biosimilar competitor to come to market between the deadline on May 22, 2023 for a Biosimilar Manufacturer to submit the documentation for its Initial Delay Request and the selected drug list publication date on September 1, 2023. A few commenters also expressed concern that CMS will not permit the Biosimilar Manufacturer to supplement its Initial Delay Request, except if CMS requests follow-up information or if the Biosimilar Manufacturer would like to update CMS on the status of the Biosimilar application for licensure before 11:59pm PT on August 15, 2023. Commenters requested that CMS set the Initial Delay Request submission deadline as close as reasonably possible to the selected drug list publication date and permit broad supplementation of a timely request with late-breaking information.

Response: CMS thanks these commenters for their feedback and reiterates that the statute is clear that an Initial Delay Request submitted with respect to initial price applicability year 2026 must demonstrate that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025. The Initial Delay Request timeline therefore does not preclude a Biosimilar from coming to market between the deadline on May 22, 2023 for a Biosimilar Manufacturer to submit the documentation for its Initial Delay Request and the selected drug list publication date on September 1, 2023 (though CMS notes that if the Biosimilar launches between May 22, 2023 and September 1, 2023, then CMS may determine the Reference Drug is not a qualifying single source drug based on the process described in section 30.1 of this revised guidance). Further, the Initial Delay Request deadline has already been set as close to the selected drug publication date as is administratively feasible. CMS adopted this timeline under the authority granted to it in section 1192(f)(1)(B)(ii) of the Act to set the time, form, and manner of Biosimilar Delay requests, and has exercised this authority to establish a timeline

(which is described in section 30.3.1.4 of the revised guidance) that allows CMS to carefully review the Initial Delay Request documentation and, if applicable, to request follow-up information from the Biosimilar Manufacturer on its Initial Delay Request. The timeline ensures that CMS will have adequate time to review follow-up data and make a well-informed determination. Regarding commenters' requests that CMS permit broad supplementation of a timely request, CMS believes that the timeline described in section 30.3.1.4 allows Biosimilar Manufacturers sufficient opportunity to provide CMS with information during the Initial Delay Request process. CMS is not able to accommodate broad supplementation of an Initial Delay Request given the ambitious statutory deadlines for implementing the Negotiation Program for initial price applicability year 2026. CMS will consider adjusting the Initial Delay Request timeline for initial price applicability year 2027 in future guidance, if feasible.

Comment: A few commenters requested that CMS create a way for a Biosimilar Manufacturer to ascertain, before the Initial Delay Request deadline, whether a Reference Drug is likely to be selected for negotiation. One commenter recommended that CMS enable a Biosimilar Manufacturer to inquire with CMS in advance of the Initial Delay Request deadline. A couple of commenters requested that CMS update the Part D Drug Spending Dashboard more frequently or direct manufacturers to other sources of publicly available information to inform assessments of the likelihood that a Reference Drug will be selected for negotiation.

Response: CMS thanks these commenters for their feedback. CMS must complete all steps of the drug selection process with fidelity, including the identification of negotiation-eligible drugs using PDE data with dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. As described in section 30.2 of this revised guidance, to allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service during this 12-month period that Part D plans have submitted to CMS no later than 30 days after May 31, 2023, i.e., by June 30, 2023. Further, to ensure that a potential qualifying single source drug does not have generic or biosimilar competition, CMS will review PDE data for the 12-month period beginning August 16, 2022 and ending August 15, 2023, using PDE data available on August 16, 2023, as well as AMP data for the 12-month period beginning August 1, 2022 and ending July 31, 2023, using the AMP data available on August 16, 2023 for a given generic drug or biosimilar biological product for which a potential qualifying single source drug is the listed drug or reference product. CMS is, therefore, unable to disclose information regarding the selected drug list in advance of the selected drug publication date due to the ambitious statutory deadline for identifying selected drugs and publishing the selected drug list.

CMS appreciates feedback received on the Part D Drug Spending Dashboard. This dashboard allows for a longer claims runout to provide time for claims to be submitted, processed, and finalized than is possible for the data that CMS is statutorily required to use to identify and rank negotiation-eligible drugs. CMS recently announced that it plans to continue its annual updates to the Drug Spending Dashboards to provide the public with comprehensive data on trends related to drug spending for Medicare and Medicaid.[12]

[12] See: https://www.cms.gov/blog/cms-drug-spending-dashboards-and-inflation-reduction-act.

Comment: A couple of commenters asked that CMS notify each Biosimilar Manufacturer that submits an Initial Delay Request of the results of such request in advance of the selected drug publication date. These commenters requested that CMS establish a mechanism by which manufacturers can dispute CMS' determination.

Response: Ambitious statutory deadlines prevent CMS from providing each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2026 with advance notice of CMS' determination regarding its request prior to the selected drug list publication date. However, CMS will notify each Biosimilar Manufacturer of CMS' determination on or after September 1, 2023, but not later than September 30, 2023. CMS does not intend to establish a dispute resolution process for Initial Delay Requests.

Comment: One commenter was uncertain whether Appendix B of the initial memorandum includes conflicting information on whether CMS will accept Initial Delay Requests that are incomplete or not timely.

Response: CMS appreciates this request for clarity and confirms that CMS will not accept Initial Delay Requests that are incomplete or not timely. CMS directs readers to section 30.3.1.4 of this revised guidance, which includes a table providing a summary of key dates related to implementation of the Biosimilar Delay for initial price applicability year 2026 as specified in section 30.3.1 of this revised guidance. The deadline for a Biosimilar Manufacturer to email CMS regarding its intent to submit an Initial Delay Request for initial price applicability year 2026 was 11:59 p.m. PT on May 10, 2023.

Comment: One commenter inquired about Question 10 of Appendix B: Template for the Initial Delay Request Form. The commenter remarked that a Biosimilar may qualify for an Initial Delay Request if its section 351(k) BLA is accepted for filing by August 15, 2023. Given FDA's 60-day filing review, the section 351(k) BLA must be submitted no later than June 16, 2023. A Biosimilar Manufacturer that has not yet submitted its section 351(k) BLA by May 22, 2023, but intends to do so by June 16, 2023, must select option (D) on the form detailed in Appendix B of the initial memorandum. The commenter requested that, to guard against any inadvertent disqualification of such Initial Delay Requests, CMS should make clear that selecting this option does not preclude eligibility for the Initial Delay Request.

Response: Selecting option (D) on the form detailed in Appendix B of this guidance does not preclude eligibility for the Initial Delay Request. Biosimilar Manufacturers have until 11:59 p.m. PT on August 15, 2023, to update CMS on the status of the Biosimilar's application for licensure.

Comment: A couple of commenters urged CMS to favor policies that support a robust biosimilars market that drives down prices for patients but did not reference any specific policies. These commenters stated that CMS should consider how to mitigate potential unintended consequences that may disincentivize the development of biosimilars and hinder a robust biosimilars market.

Response: CMS firmly supports a robust biosimilars market and believes that the policies for implementing the special rule to delay selection and negotiation of biologics for biosimilar

market entry will help support biosimilar entry and price competition in the biosimilars market. CMS welcomes input on specific approaches to monitor for potential unintended consequences of these policies and may consider modifications if necessary to mitigate any unintended impact.

Medicare Drug Price Negotiation Program Agreement (Sections 40, 40.1, and 40.6)

Comment: One commenter commented that the statute defines manufacturer by reference to section 1847A(c)(6)(A) of the Act and requested that CMS clarify the definition of Primary Manufacturer as it pertains to the very broad statutory definition.

Response: CMS thanks this commenter for the recommendation. Section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug, and the phrase "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program. The best statutory interpretation is to interpret the term "manufacturer" as a single entity for the negotiation process, responsible for negotiating the maximum fair price for a given selected drug. As described in section 40 of this revised guidance and pursuant to section 1191(c)(1) of the Act, to the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" (referred to in this revised guidance as the Primary Manufacturer) of the selected drug.

Comment: Some commenters requested that CMS remove requirements related to Secondary Manufacturers because they view such requirements as inconsistent with CMS' past interpretation of the definition of "manufacturer" in Section 1927(k)(5) of the Act.

Response: CMS appreciates commenters' feedback. In previous interpretations of other provisions of the Act, CMS has expressed concern with burdening manufacturers with no relationship to the holder of an NDA / BLA. In this revised guidance, CMS reiterates its position to exclusively limit any requirements with respect to the terms of the Agreement to manufacturers listed on the NDA / BLA, or manufacturers that market the selected drug pursuant to an agreement with the Primary Manufacturer. Any requirements placed on the Primary Manufacturer by the Negotiation Program to address Secondary Manufacturer actions are solely related to its voluntarily assumed relationship.

CMS also notes that, under the Negotiation Program, Primary Manufacturers enter into an agreement to negotiate an MFP with CMS and to provide access to that MFP for the selected drug, including sales of the selected drug by Secondary Manufacturers. Harm to competition from Primary Manufacturers ensuring MFP availability in sales by Secondary Manufacturers is unlikely because the requirement to provide access to the MFP is mandated by the Negotiation Program and not imposed by the Primary Manufacturer, and because accepting that approach is a requirement of the Negotiation Program. Moreover, the Negotiation Program offers operational flexibility to manufacturers and would not restrict the Primary Manufacturer or Secondary Manufacturer(s) from offering the selected drug at a price lower than the MFP. For these reasons, applying the MFP to sales by Secondary Manufacturers is unlikely to create a situation inconsistent with the antitrust laws.

Comment: In connection with their feedback on the Secondary Manufacturer policies, a few commenters cited the provisions of a 2007 Medicaid Drug Rebate Program (MDRP) rule relating to the treatment of authorized generic drugs. A few commenters also cited a provision from a 2016 MDRP rule relating to the treatment of line extensions.

Response: CMS thanks these commenters for their input. This revised guidance echoes the relationship between manufacturers in the 2007 and 2016 MDRP rules. This revised guidance defines a Secondary Manufacturer as either listed as a manufacturer in the NDA or BLA or marketing the selected drug pursuant to an agreement with the Primary Manufacturer. As it relates to the comments regarding the 2016 MDRP rule, in which the primary concern expressed by commenters involves unrelated manufacturers, CMS notes that the initial memorandum focuses on Secondary Manufacturers with agreements with the Primary Manufacturer thereby limiting the applicability of those concerns. More generally, the 2007 and 2016 MDRP rules suggest that CMS has previously interpreted the statutory definition of "manufacturer" at section 1927(k)(5) of the Act to apply to situations involving multiple manufacturers in a manner that is consistent with the IRA initial memorandum policy of imposing obligations on a Primary Manufacturer with regard to Secondary Manufacturers. Where differences remain under which the Negotiation Program imposes more substantial obligations on the Primary Manufacturer for commercial practices and data of Secondary Manufacturers, these differences are supported by the text, scope, and purpose of the IRA.

Comment: One commenter questioned whether CMS' definition of Secondary Manufacturer could include firms that do not meet the statutory definition of manufacturer with respect to the selected drug but have a marketing agreement in place with the Primary Manufacturer.

Response: CMS thanks this commenter for their input. As described in section 40 of this revised guidance, for initial price applicability year 2026, CMS will refer to any entity other than the Primary Manufacturer that meets the statutory definition of manufacturer, under section 1191(c)(1) of the Act, for a drug product included in the selected drug, and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer, as a Secondary Manufacturer. Secondary Manufacturers will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meets these criteria, including those entities that have a marketing agreement with the Primary Manufacturer. A firm that does not meet the statutory definition of a manufacturer under section 1191(c)(1) of the Act does not meet CMS' definition of a Secondary Manufacturer.

Comment: Several commenters requested that CMS provide a comment period for the Medicare Drug Price Negotiation Program Agreement (herein referred to as the "Agreement") to allow manufacturers and the public the opportunity to review and comment on the Agreement. A few commenters expressed concern that lack of advance notice could result in a manufacturer's inability to establish appropriate processes prior to the Agreement's effective date, resulting in possible noncompliance. A couple of commenters also stated that there are only three options for manufacturers within the Negotiation Program under the IRA: sign the Agreement, pay the excise tax, or leave Medicare and Medicaid. Manufacturers expressed concern with the lack of options available to a manufacturer that chooses not to sign the Agreement.

Response: In section 40 of the initial memorandum, CMS included descriptions of and solicited comments on the Agreement requirements to provide interested parties an opportunity to comment on these requirements. Given the thoughtful and extensive comments CMS received on these requirements, CMS determined to set forth the parameters of the manufacturer's obligations under the Negotiation Program in this revised guidance, while reserving for the Agreement certain general provisions and term and termination provisions. The decision to not separately repeat the program requirements in the Agreement means that the program requirements applicable to a manufacturer of a selected drug that enters into an Agreement for initial price applicability year 2026 are preserved and presented in this revised guidance for which there has been public notice and comment. In light of the complexity of the actions the agency must undertake in advance of the Agreement being signed by the statutory deadline of October 1, 2023, CMS will not provide a comment period on the Agreement. However, CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list is published for initial price applicability year 2026. Please see the responses to comments below for a discussion of the options available to manufacturers who choose not to participate in the Negotiation Program.

Comment: One commenter asked that CMS provide manufacturers with information on how CMS plans to monitor compliance with the Agreement and allow for manufacturers to provide feedback on this information.

Response: The initial memorandum and subsequent revised guidance provide information on how CMS plans to monitor compliance with the Agreement, including the requirements within this revised guidance. As described in section 90.1 of this revised guidance, CMS will provide information about the negotiation process to the Primary Manufacturer of each selected drug. CMS anticipates this information will include operational and statutory timelines, procedural requirements, system instructions, IRA resources, and contact information. During the negotiation period, CMS plans to track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer, including as it relates to compliance. CMS is committed to supporting compliance with program requirements and will provide written reminders and warnings of potential noncompliance (described in section 90.1 of this revised guidance). Following the conclusion of negotiations, CMS plans to monitor compliance related to the Primary Manufacturer's obligations to provide access to the MFP, as described in section 40.4 and section 90.2 of this revised guidance.

As described in section 40.5 of this revised guidance, in monitoring compliance, CMS may engage in auditing processes to verify the accuracy and completeness of any information provided by the Primary Manufacturer, as well as any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by any Secondary Manufacturer(s).

Comment: A few commenters stated that CMS should not require Primary Manufacturers to submit points of contact for the Agreement within five calendar days of publishing selected drugs, as this process is not included in statute. Commenters noted that CMS should state its

authority in developing this timeline and clarify implications of noncompliance with this timeline.

Response: CMS thanks these commenters for their feedback. CMS revised its policy in section 40.1 of this revised guidance regarding providing points of contact. CMS recommends but does not require this action be taken within five days following publication by CMS on September 1, 2023 of the list of selected drugs and prior to the Agreement being signed to facilitate communication between CMS and the Primary Manufacturer and support efficient effectuation of the Agreement. Primary Manufacturers must provide points of contact by October 1, 2023 at the time that the Agreement is signed.

Comment: A few commenters suggested that CMS consider different ways to designate a Primary Manufacturer other than the holder of the NDA / BLA, given scenarios like split licensures and acquisitions. Commenters recommended CMS consider using the FDA product labeler ID to determine the manufacturer for purposes of negotiating the MFP.

Response: When an application to market a new drug or biological product for human use is submitted to the FDA, the NDA / BLA that is submitted lists only one sponsor. The policy for identifying the Primary Manufacturer with responsibility for the selected drug based on the holder of the NDA / BLA for the selected drug under the Negotiation Program is consistent with the FDA regulatory framework under which the single sponsor of the NDA / BLA in its application describes the manufacturing process and lists the facilities that will produce the sponsor's product. In section 1191(c)(1) of the Act, the statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. CMS understands that the holder of an NDA or BLA can enter into agreements regarding the sale of drugs approved under a particular NDA or BLA with other entities that may also meet this statutory definition of "manufacturer." CMS must find a mechanism to identify the appropriate manufacturer for purposes of negotiation and ensure other aspects of the Negotiation Program apply to the selected drug. In addition, section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug and the term "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program. The best statutory interpretation is to interpret the term "manufacturer" as a single entity for the negotiation process, responsible for negotiating the maximum fair price for a given selected drug. Thus, the most effective way to determine the "manufacturer" described in section 40 of this revised guidance, and the signatory of the Agreement, is to identify the NDA / BLA holder as the Primary Manufacturer.

Comment: Many commenters made recommendations pertaining to the Agreement and how it applies to Secondary Manufacturers. Commenters recommended CMS require all Secondary Manufacturers to sign the same Agreement that applies between Primary Manufacturers and CMS. A few commenters suggested that Secondary Manufacturers sign a unique Agreement with CMS in addition to the Agreement between Primary Manufacturers and CMS. A few commenters were supportive of CMS' policy to enter into an Agreement with only the Primary Manufacturer.

Response: Given that section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug to which "the manufacturer" would provide access in accordance with the statute, and given that the term "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program, the best statutory interpretation is to interpret the term "manufacturer" as a single entity for the negotiation process, responsible for negotiating a single maximum fair price for a given selected drug. Thus, in accordance with section 1193(a)(1) of the Act and other statutory references to "the manufacturer," CMS will enter into an Agreement with "the manufacturer" of a selected drug, where "the manufacturer" is the NDA / BLA holder as described in section 40 of this revised guidance. CMS has adopted the designations of "Primary Manufacturer" and "Secondary Manufacturer," respectively, to establish a process to negotiate the maximum fair price with "the manufacturer" to align with the meaning of the statutory language and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and MFP availability for the selected drug sold by the Secondary Manufacturer(s).

Comment: One commenter asked CMS to clarify whether a Primary Manufacturer is only responsible for data submission and MFP availability for sales of the selected drug by a Secondary Manufacturer when there is a contractual agreement between the two parties.

Response: CMS thanks this commenter for their question. For initial price applicability year 2026, a Primary Manufacturer will be responsible for data submission and MFP availability for sales of the selected drug by a separate manufacturer of the selected drug if that separate manufacturer is a Secondary Manufacturer as described in section 40 of this revised guidance. An entity is a Secondary Manufacturer if it meets the statutory definition of a manufacturer for the selected drug and either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer. Specifically, any manufacturer that qualifies as a Secondary Manufacturer for initial price applicability year 2026 will have an existing relationship with a Primary Manufacturer. A Secondary Manufacturer will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug.

Comment: A few commenters stated that CMS should allow each Secondary Manufacturer to participate in all negotiation activities, including negotiation meetings, and have access to all written correspondence between the Primary Manufacturer and CMS. If CMS chooses not to allow this, the Primary Manufacturer should be allowed to share any and all documentation with the Secondary Manufacturer.

Response: The best statutory interpretation is to interpret the term "the manufacturer" as a single entity for the negotiation process responsible for negotiating a single maximum fair price for a given selected drug. In addition, section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug, and the phrase "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program. Congress's use of the singular definite article demonstrates that, for any one selected drug, the "manufacturer" with which CMS negotiates is a single entity. Thus, CMS believes that the most effective way to determine the "manufacturer" described in section 40 of the guidance and the signatory of the Agreement, is to identify the NDA / BLA holder as the

Primary Manufacturer. CMS has adopted the designations of "Primary Manufacturer" and "Secondary Manufacturer," respectively, to establish a process to negotiate an MFP with a single manufacturer to align with the meaning of the statutory language "the manufacturer," and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and ensuring MFP availability for selected drug sold by the Secondary Manufacturer(s).

As described in section 40.2.2 and 60.6.1 of this revised guidance, CMS does not intend to publicly discuss the negotiation process prior to the public explanation of the MFP being released, unless a Primary Manufacturer discloses information that is made public. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. Primary Manufacturers engaged in negotiating an MFP with CMS are reminded that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. Primary Manufacturers should consider the antitrust implications of any such actions. CMS will protect the confidentiality of any proprietary information from Primary Manufacturers or Secondary Manufacturers (described in section 40.2.1) as required under section 1193(c) of the Act and other applicable law. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this revised guidance. Neither the IRA nor this revised guidance prevents Primary Manufacturers from disclosing any information to Secondary Manufacturers.

Comment: One commenter stated that CMS should revise the National Drug Rebate Agreement and the Coverage Gap Discount Program Agreement, and work with the Health Resources and Services Administration (HRSA) to revise the Pharmaceutical Pricing Agreement, to permit immediate termination from all applicable federal programs in the event that an agreement on an MFP cannot be reached or a manufacturer is dissatisfied with the MFP.

Response: CMS thanks this commenter for their recommendation. CMS has clarified in section 40.6 of the revised guidance that a Primary Manufacturer that decides not to participate in the Negotiation Program may voluntarily terminate the Medicare Drug Price Negotiation Program Agreement if it also ceases participation in the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program through the end of the price applicability period for the selected drug. CMS has also clarified in section 40.1 of the revised guidance that a Primary Manufacturer that elects not to participate in the Medicare Drug Price Negotiation Program may take similar measures to cease its participation in the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program. Sections 40.1 and 40.6, as revised, set forth the procedures for the Primary Manufacturer to initiate termination processes under the Medicare and Medicaid programs and the steps CMS will take to facilitate an expeditious termination of the Primary Manufacturer's agreements under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable. As a result of these procedures, any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting

the notice and termination requests described herein 30 days in advance of the date that excise tax liability otherwise may begin to accrue. Moreover, any manufacturer that has entered into an Agreement will retain the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability.

Manufacturer Data Submission, Proprietary Information, and Confidentiality (Section 40.2)

Comment: Several commenters requested that CMS not publish any proprietary information in the MFP public explanation and continue to provide strong protections to proprietary data otherwise collected under Part D. Several commenters also stated that CMS should give manufacturers the opportunity to review, raise concerns, and designate any information therein that is confidential and proprietary in advance of the publication of the public explanation of the MFP. A few commenters stated that CMS should clarify that any proprietary information shall be disclosed or exclusively used by CMS or the Comptroller General of the United States only for IRA-related purposes, and not used or disclosed for any other reason, regardless of whether the requirements of the Freedom of Information Act (FOIA) are satisfied.

Response: Section 1193(c) of the Act requires that information submitted to CMS by the manufacturer of a selected drug that is proprietary information, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. CMS is committed to protecting confidential and proprietary information obtained from manufacturers throughout the negotiation process. In addition, CMS is also committed to protecting information that is obtained from Prescription Drug Plans (PDPs) and MA-PD plans that will inform the negotiation process. For initial price applicability year 2026, as described in section 40.2.1 of this revised guidance, CMS will treat information on non-FAMP as proprietary, as well as treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with sections 1194(e)(1) and 1194(e)(2) of the Act as proprietary, if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that meets the requirements set forth under Exemptions 3 and/or 4 of FOIA (5 U.S.C. § 552(b)(3), (4)). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. § 1905 requires executive branch employees to protect such information. CMS understands commenters' concerns pertaining to the confidentiality of proprietary information and will protect confidential and proprietary information as required by applicable law. However, if a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this guidance.

Comment: Some commenters stated that CMS should remove, or at least modify, the data destruction requirements within the confidentiality policy for manufacturers following the deselection of a selected drug. One commenter stated that CMS should consider removing the 30-day timeline for data destruction, or let manufacturers petition for an extension. Other commenters stated that CMS should impose parallel data destruction requirements or revise the policy to align with other federal programs.

Response: After reviewing these comments and further consideration of the issue, CMS has removed the data destruction requirements under the confidentiality policy described in section 40.2.2 of this revised guidance pertaining to Primary Manufacturers.

Comment: Many commenters requested that CMS clarify whether specific data elements submitted by Primary Manufacturers (including, where applicable, Secondary Manufacturer data submitted by the Primary Manufacturer) will be released publicly. Commenters asked that CMS aggregate and release information about prior Federal financial support, approved patents, exclusivities, approvals, aggregate estimates or deidentified research and development costs, historic sales, volume of sales, revenue, and market data of selected drugs. Commenters requested that CMS clarify that information that is publicly available will not be deemed proprietary.

Response: CMS thanks these commenters for their input. As stated in section 40.2.2 of the revised guidance, CMS revised the confidentiality policy for the negotiation process in response to comments received and further consideration of the issue. In the interest of balancing transparency and confidentiality, CMS has made revisions in the guidance pertaining to what information CMS will keep confidential and for how long. As described in section 40.2.2 and 60.6.1 of this revised guidance, as a part of the public explanation of the MFP published in March 2025, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings. CMS maintains that any information submitted by manufacturers that constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer will be considered proprietary and will be redacted.

A Primary Manufacturer may choose to publicly disclose information regarding any aspect of the negotiation process at any time, including prior to the public explanation of the MFP being released by CMS. Of note, while CMS generally plans to wait to release information about the negotiation process until CMS publishes the public explanation of the MFP, if the Primary Manufacturer chooses to disclose information prior to the publication of the public explanation of the MFP, CMS may decide to make early disclosures about the negotiation process as well.

Comment: One commenter stated that CMS should clarify what elements of the Biosimilar Initial Delay Request will be exempt from any FOIA requests or disclosures.

Response: CMS revised section 30.3.1 of this revised guidance to clarify that information in an Initial Delay Request and in a Small Biotech Exception ICR Form that is a trade secret or confidential commercial or financial information will be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of FOIA (5 U.S.C. § 552(b)(3), (4)).

Comment: One commenter stated that CMS should clarify that the existence and status of a pending NDA or BLA, in addition to information contained in a pending NDA or BLA, will be treated as proprietary information.

Response: As stated in the initial memorandum, for initial price applicability year 2026, CMS will treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. It is CMS' presumption that a pending NDA or BLA would qualify as proprietary under this standard.

Comment: One commenter asked CMS to release the full negotiation records five to ten years after the patents for a selected drug expire.

Response: As stated in section 40.2.2 of this revised guidance, CMS revised the confidentiality policy for the negotiation process in response to comments received and after further consideration of the issue. In the interest of balancing transparency and confidentiality, CMS has made revisions in the guidance pertaining to what information CMS will keep confidential and for how long. As described in sections 40.2.2 and 60.6.1 of this revised guidance, as a part of the public explanation of the MFP published in March 2025, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings.

At this time, CMS is issuing guidance for implementation of initial price applicability year 2026 and does not foresee that CMS would subsequently provide additional disclosure in the manner the commenter is suggesting. CMS will continue to consider whether such additional disclosure is appropriate in the future.

Comment: One commenter asked CMS to clarify the consequences for violating the requirements of confidentiality for both manufacturers and CMS.

Response: CMS thanks this commenter for their input. In the interest of balancing transparency and confidentiality, CMS revised the confidentiality policy for the negotiation process in response to comments received and further consideration of the issue. CMS does not intend to publicly discuss the negotiation process prior to the public explanation of the MFP being released, unless a Primary Manufacturer chooses to discuss the negotiation publicly. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. Primary Manufacturers engaged in negotiating an MFP with CMS are reminded that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. Primary Manufacturers should consider the antitrust implications of any such actions.

The Trade Secrets Act at 18 U.S.C. § 1905 requires executive branch employees to protect proprietary information. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary

Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this revised guidance.

Comment: One commenter asked how CMS will enforce the confidentiality requirements for individuals who no longer work at a manufacturer of a selected drug or at CMS.

Response: CMS thanks this commenter for their question. In the interest of balancing transparency and confidentiality, CMS revised the confidentiality policy for the negotiation process in response to comments received and further consideration of the issue. Primary Manufacturers have the authority to determine how former employees may use or discuss its proprietary information as it pertains to the Negotiation Program. CMS employees that leave CMS are informed prior to their departure that they are not permitted to disclose nonpublic information obtained as a result of CMS employment that has not been released to the public.

Comment: Many commenters stated that the confidentiality policy as described in the initial memorandum violates the First Amendment rights of manufacturers, is not supported by statute, or is not necessary to administer or monitor compliance with the Negotiation Program. One commenter asked that CMS align the confidentiality policy so manufacturers and CMS are bound by the same confidentiality standards. Many commenters raised concerns that the confidentiality policy would prevent manufacturers from disclosing to their board and investors pertinent information related to the negotiation process. One commenter asked CMS to make all offers and counteroffers public. A few commenters were supportive of CMS' confidentiality policy as it is consistent with private sector negotiation processes.

Response: CMS thanks these commenters for their input. As stated in section 40.2.2 of the revised guidance, CMS revised the confidentiality policy for the negotiation process in response to comments received and upon further consideration of the issue. In the interest of balancing transparency and confidentiality, CMS has made revisions pertaining to which information CMS will keep confidential and for how long in the revised guidance. As described in sections 40.2.2 and 60.6.1 of the revised guidance, as a part of the public explanation of the MFP published in March 2025, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings. CMS maintains that any information submitted by manufacturers that constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer will be considered proprietary and will be redacted.

A Primary Manufacturer may choose to publicly disclose information regarding any aspect of the negotiation process at any time, including prior to the explanation of the MFP being released by CMS. Of note, while CMS generally plans to wait to release information about the negotiation process until CMS publishes the explanation of the MFP, if the Primary Manufacturer chooses to disclose information about the negotiation process prior to the publication of the public explanation of the MFP, CMS may decide to make early disclosures about the negotiation process as well. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer,

CMS will no longer consider that material proprietary consistent with section 40.2.1 of this revised guidance.

Comment: One commenter stated that CMS should allow manufacturers to negotiate the scope and terms of any confidentiality policies, including whether manufacturers may publicly discuss the Negotiation Program, as a part of the broader negotiation process.

Response: CMS thanks this commenter for their input. In the interest of balancing transparency and confidentiality, CMS made revisions in the guidance to clarify that a Primary Manufacturer may publicly disclose information regarding the Negotiation Program, as described in section 40.2.2 of this revised guidance. In section 40.2 of this revised guidance, CMS describes a confidentiality policy that applies to all Primary Manufacturers of selected drugs who choose to sign an Agreement. Adopting a standard confidentiality policy allows CMS to focus the negotiations on the statutory goal of negotiating to achieve agreement on the lowest MFP and creates uniform protection of information determined to be proprietary as well as transparency upon the release of the explanation of the MFP.

Comment: One commenter asked CMS to consider revising the policies for classification and handling of proprietary data in the coming years and re-evaluate whether this approach should be applied to a narrower set of data elements.

Response: CMS thanks this commenter for their input and will take the comment under advisement as CMS considers policies for future years of the Negotiation Program.

Comment: A few commenters asked how CMS plans to secure manufacturer-submitted data. Commenters asked CMS to outline a cybersecurity policy regarding how CMS plans to implement safeguards to protect manufacturer-submitted data, how such data will be stored, and a process for alerting manufacturers of any breach or erroneous use.

Response: CMS thanks these commenters for their comments on safeguarding data submitted by manufacturers. Primary Manufacturers will submit the information to CMS via the Health Plan Management System ("CMS HPMS"). The CMS HPMS adheres to all applicable policies, procedures, controls, and standards required by the Department of Health and Human Services (HHS)/CMS information security and privacy programs to ensure the confidentiality, integrity, and availability of manufacturer information and government information systems. The CMS HPMS system is the primary CMS system for exchange of information between CMS and Medicare Advantage and Medicare Prescription Drug Plans, and as such is designed to receive and keep confidential proprietary and commercially sensitive information.

As required by CMS, the CMS HPMS integrates security into every aspect of the system development life cycle. The CMS HPMS is subject to the agency's Security Assessment and Authorization (SA&A) process, a rigorous methodology during which the system must demonstrate a sound and comprehensive information security posture. In order to achieve and maintain an Authority to Operate (ATO), the CMS HPMS routinely undergoes system penetration testing as well as a Security Control Assessment (SCA), where independent auditors

perform a detailed assessment to ensure that the system's security controls meet the CMS Acceptable Risk Safeguards (ARS).

An individual must apply for and obtain a CMS-issued user account and password in order to access the CMS HPMS. In addition to the CMS-issued user ID and password, internal CMS staff must use an HHS identification badge (referred to as a PIV card) when accessing the website on the CMS network, while all users accessing the system from outside of the CMS network must use multi-factor authentication. The CMS HPMS further employs role-based access, ensuring that each user is granted access only to those functions required by their position.

The CMS HPMS is hosted at a CMS approved cloud service provider. The system is protected by a suite of firewall and intrusion detection services, including Akamai Content Delivery Network (CDN), which serves as an additional web application firewall that offers robust distributed denial of services protection and access control. The CMS HPMS utilizes a multi-zone architecture comprised of a presentation zone, an application zone, and a data zone, designed to provide further defense against security attacks. CMS will employ encryption at rest in the database for sensitive manufacturer data (e.g., proprietary information, including trade secrets and confidential commercial or financial information) in addition to encryption in transit.

The CMS HPMS adheres to the CMS Information Security Incident Handling Procedures, which are supplemented by the CMS HPMS Security Incident Handling Procedures. These documents outline the procedures for managing known or suspected security or privacy incidents, including, but not limited to, roles and responsibilities, escalation procedures, and guidelines for notifying impacted individuals or organizations.

Negotiation and Agreement to an MFP and Renegotiation in Later Years (Section 40.3)

Comment: One commenter noted that CMS has not outlined the specific conditions under which a renegotiation will occur in subsequent years.

Response: CMS thanks this commenter for the comment. This guidance includes details regarding the Negotiation Program for initial price applicability year 2026. CMS will provide additional information in the future for initial price applicability years 2027 and beyond, including renegotiation, which will be implemented for initial price applicability year 2028 and subsequent years, in accordance with the statute.

Access to the MFP (Sections 40.4 and 90.2)

Comment: One commenter expressed concern that the MFP would be adopted as a reference price by non-Medicare payers. For example, commercial plans and PBMs might use a selected drug's MFP to inform negotiations or to establish payment and reimbursement amounts for the selected drug outside of the Medicare program.

Response: The IRA directs CMS to negotiate an MFP for each selected drug for the Medicare program and requires the manufacturers of such drugs to make the MFP available to MFP-eligible individuals. As discussed in section 80 of this revised guidance, for initial price

applicability year 2026, Primary Manufacturers of selected drugs must provide access to the MFP for a selected drug to Medicare beneficiaries who use their Part D plan (including an MA-PD plan under Medicare Part C or an Employer Group Waiver Plan, but not a plan that receives the Retiree Drug Subsidy) if Part D coverage is provided under such plan for such selected drug. The Negotiation Program does not regulate payment rates by payers outside of the Medicare program (e.g., in the commercial markets). CMS will publish the MFP for each selected drug, as required by law. The MFP for each selected drug could be published by pharmaceutical pricing database companies and could be used by other payers for reimbursement and other purposes. Payers will continue to have discretion to consider Medicare payment rates among other considerations in establishing their own payment policies. CMS notes that Medicare already establishes and publishes payment rates for drugs under Part B using the Average Sales Price (ASP) methodology that may be used by other payers (such as state Medicaid programs), and Medicaid also publishes various pharmaceutical pricing benchmarks, such as the National Average Drug Acquisition Cost (NADAC) file and Federal Upper Limits (FULs) for multiple source drugs, that may be used by other payers.

Comment: Many commenters provided perspectives and recommendations regarding CMS' policies in the initial memorandum to monitor access to the MFP. Many commenters recommended CMS require manufacturers to use a retrospective MFP refund approach to adjust reimbursement to pharmacies, mail order services, and other dispensing entities for dispensing a selected drug to an MFP-eligible individual. Many commenters recommended CMS help effectuate a retrospective refund model by contracting with a third-party administrator (TPA) or clearinghouse to facilitate data and/or payment exchange between entities in the supply chain so pharmacies, mail order services, and other dispensing entities receive retrospective refunds in a timely manner. Many commenters recommended that, in contracting with a TPA, CMS include processes to allow manufacturers to avoid providing the 340B price and an MFP refund for the same unit(s) of a selected drug dispensed to an MFP-eligible individual.

Response: CMS thanks these commenters for the recommendations. CMS intends to engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between supply chain entities to verify eligibility of MFP-eligible individuals. CMS appreciates the value of the role an MTF could play in supporting the identification of selected drugs dispensed to MFP-eligible individuals to facilitate appropriate retrospective reimbursement by manufacturers. CMS is also exploring options to facilitate retrospective payment exchange between interested parties to help effectuate access to the MFP. CMS is committed to the goal of ensuring prompt payment to dispensers for pass through of the MFP, consistent with other prompt pay rules in Part D.[13] Pursuant to section 40.4 of this revised guidance, CMS requires that the MFP be passed through to dispensers within 14 days of the manufacturer receiving sufficient information to verify that an individual is eligible for access to the MFP. With respect to the establishment of a process to allow manufacturers to avoid providing a 340B price and an MFP for the same unit of drug, CMS understands the value of the identification of 340B units for the Negotiation Program and the Part D Drug Inflation Rebate Program. CMS intends to examine options with respect to identification of 340B units and intends to work with HRSA accordingly. CMS has revised sections 40.4 and 90.2 of this revised guidance to include further detail regarding access

[13] See 42 C.F.R. § 423.520, Prompt Payment by Part D Sponsors, which requires Part D sponsor payment to pharmacies within 14 days after receiving a Part D claim and determining that the Part D claim is a clean claim.

to the MFP and will provide more information in advance of initial price applicability year 2026.

Comment: Some commenters recommended that CMS define the amount of the MFP refund that is due from the manufacturers to the pharmacies. Some advocated for a retrospective "true up" payment from the manufacturer to the dispensing entity, using a standardized amount, such as the difference between a publicly reported pricing metric (such as WAC) and the MFP, rather than a dispensing entity's actual acquisition cost for the selected drug. One commenter recommended CMS use the annual non-FAMP as the standardized metric.

Response: CMS thanks these commenters for their recommendation. The majority of the comments received from supply chain entities on this topic, including manufacturers and pharmacies, supported the use of a standardized, published pricing metric to calculate the refund due from the manufacturer to the pharmacy or other dispenser for the pass through of the MFP. After reviewing the comments and further consideration of the topic, CMS is exploring the option of allowing manufacturers to use a standardized refund amount, such as the WAC of the selected drug minus the MFP (WAC-MFP). CMS plans to provide further information regarding this topic in technical guidance before initial price applicability year 2026.

Comment: Some commenters recommended CMS regularly monitor whether Primary or Secondary Manufacturers are compliant with the requirements of the Negotiation Program, including providing access to the MFP. One commenter recommended CMS create an online option and phone options for reporting violations related to access to the MFP with respect to MFP-eligible individuals. One commenter recommended CMS set a time limit to respond to individuals reporting violations, report the number of complaints CMS receives, and create an ombudsman to serve as a point of contact for individuals submitting complaints.

Response: CMS thanks these commenters for their recommendations, including those relating to the importance of having multiple avenues for reporting violations and timely resolution of investigating such complaints. As further described in sections 40.4 and 90.2 of this revised guidance, CMS will closely monitor the Primary Manufacturers' compliance with the terms of the Agreement and other aspects of the Negotiation Program, including whether the Primary Manufacturer is ensuring that the MFP is available for the selected drug sold by Secondary Manufacturers, where applicable. CMS will establish procedures by which individuals, as well as pharmacies, mail order services, and other dispensing entities, will be able to report instances to CMS in which the MFP should have been made available but was not. CMS will respond to reports of violations in a timely manner, and plans to issue more information on reporting procedures in advance of initial price applicability year 2026.

Comment: A few commenters recommended that CMS establish a financially viable model for pharmacy reimbursement when a pharmacy dispenses a selected drug to an MFP-eligible individual, including by requiring a dispensing fee that covers a pharmacy's business operation costs to dispense a selected drug. A couple of commenters recommended that CMS clarify that claims paid for a selected drug must be excluded from pharmacy DIR or other fees imposed by entities in the supply chain. A couple of commenters recommended CMS prohibit PBMs, Part D plan sponsors, or other entities in the supply chain from charging administrative fees to

manufacturers or pharmacies for providing access to a selected drug. One commenter recommended CMS require higher dispensing fees for entities dispensing a selected drug.

Response: CMS thanks these commenters for their recommendations. Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for such drug. CMS intends to allow manufacturers to use either a prospective upfront discount model or a retrospective refund model to make the MFP available. After reviewing the comments and further consideration of the topic, CMS is working with interested parties to explore developing a standard retrospective rebate model process that would allow for the pass through of the MFP for a selected drug by manufacturers to dispensing entities for dispensing a selected drug to an MFP-eligible individual. As noted above, CMS intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to verify eligibility of MFP-eligible individuals under a retrospective rebate model. As described in section 40.4 of this revised guidance, neither Primary Manufacturers nor their contracted entities shall charge any transaction fee to dispensing entities for the pass through of the MFP to the dispenser.

Provided that Part D plans comply with all applicable requirements, plan sponsors retain flexibility in determining the fees paid or charged to pharmacies, including dispensing fees. However, CMS is committed to the goal of assuring prompt payment to pharmacies and other dispensers for passing through the MFP, consistent with other prompt pay rules in Part D, and is requiring manufacturers to pass through the MFP within 14 days of confirming an individual is eligible for the MFP. Please refer to sections 40.4 and 90.2 of this revised guidance for more information.

Comment: Some commenters recommended CMS collaborate with interested parties to implement a single process for manufacturers to provide access to the MFP that works for entities across the pharmaceutical supply chain. A few commenters recommended CMS work with interested parties in the pharmaceutical supply chain to develop standards for facilitating the transaction of the MFP refund.

Response: CMS thanks these commenters for their recommendations. Consistent with section 40.4 of this revised guidance, Primary Manufacturers must provide access to the MFP by either (1) ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP, or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. However, CMS notes that the majority of the commenters support the retrospective rebate or refund approach. CMS intends to engage with an MTF that could assist with data facilitation in a retrospective rebate model. CMS has been working with, and plans to continue working with, interested parties to explore processes for facilitating data exchange while minimizing burden.

Comment: A few commenters supported the options CMS outlined in the initial memorandum for providing access to the MFP. One commenter recommended CMS incentivize manufacturers to prospectively effectuate access to the MFP by making the MFP available to dispensing entities at the point of acquisition of a selected drug. One commenter recommended CMS require

manufacturers to create secondary NDCs for selected drugs and make secondary NDCs available to wholesalers at the MFP.

Response: CMS thanks these commenters for their recommendations. The majority of commenters supported a retrospective refund or rebate approach to making pharmacies, mail order services, and other dispensers whole with respect to the pass through of the MFP. CMS intends to engage with an MTF to help facilitate data exchange to confirm MFP-eligibility to provide access to the MFP using a retrospective approach for pharmacies, mail order services, and other dispensers. CMS is not requiring manufacturers to create secondary NDCs for selected drugs and the assignment of labeler codes is the responsibility of the FDA. Moreover, the NDCs for the dosage forms and strengths of a selected drug will be published on the CMS website, and CMS expects that pharmaceutical drug pricing compendia will also publish them.

Comment: Some commenters recommended CMS share detailed Part D claims data with manufacturers to verify that an individual is eligible to receive a selected drug at the MFP. One commenter recommended CMS minimize the data shared with manufacturers and other entities in the supply chain while facilitating access to the MFP.

Response: CMS thanks these commenters for their recommendations. CMS agrees that a Primary Manufacturer should be able to verify that a selected drug was dispensed to an MFP-eligible individual. As further described in sections 40.4 and 90.2 of this revised guidance, after consideration of the comments, CMS plans to release more information in advance of initial price applicability year 2026 regarding how CMS might support and facilitate data exchange between pharmaceutical chain entities.

Comment: A couple of commenters recommended that CMS require Primary Manufacturers to report the MFP of a selected drug and the effective date for the MFP in standard drug pricing compendia.

Response: CMS thanks these commenters for their recommendation. CMS will publish the MFP at the per-unit level for the dosage forms and strengths for a selected drug and keep this list up-to-date over time on the CMS IRA website. CMS anticipates that various drug pricing compendia will decide to include the MFP in their pricing files.

Comment: Some commenters recommended CMS remove or lengthen the requirement for retrospective payment to dispensing entities be made within 14 days, due to operational complexities. Some commenters recommended CMS clarify that the 14-day reimbursement requirement begins when the claim is verified for an MFP-eligible individual. One commenter recommended that CMS clarify that the 14-day reimbursement period begins when the Primary Manufacturer receives the request for reimbursement.

Response: CMS thanks these commenters for their recommendations. CMS will apply the standards set forth in current Part D prompt pay reimbursement regulations regarding payment by plan sponsors to pharmacies to manufacturers for their pass through of the MFP for selected drugs. That is, CMS will require that a Primary Manufacturer ensure that pharmacies, mail order services, and other dispensers are reimbursed timely for the pass through of the MFP within 14

days of verifying eligibility of an MFP-eligible individual. This will ensure that pharmacies are paid for the claim for the selected drug in the same timeframe as if the entire claim would have been filled through the regular Part D process. Please see sections 40.4 and 90.2 of this revised guidance for more information.

Comment: Many commenters made recommendations regarding CMS policy relating to non-duplication of the MFP and the 340B ceiling price. One commenter recommended CMS clarify that the same unit(s) of a drug dispensed to an MFP-eligible individual is not eligible for a duplicate 340B discount. A few commenters wrote that it is burdensome for pharmacies and dispensing entities to identify 340B units proactively or retroactively to avoid duplication of the MFP and 340B ceiling price. Some commenters recommended CMS contract with a TPA to identify 340B units at the point of sale or during retrospective reimbursement. A few commenters recommended CMS condition claims payment for units of selected drugs on including an accurate 340B or non-340B claim modifier. A few commenters recommended CMS work with HRSA to ensure the MFP for a selected drug is not applied to a drug that was acquired at the 340B ceiling price. Some commenters recommended CMS implement an oversight system to audit selected drug units dispensed at the MFP and identify if the same units of a selected drug were acquired at the 340B ceiling price.

Response: CMS thanks these commenters for their recommendations. CMS reiterates, as described in section 40.4.1 of the initial memorandum, that a manufacturer that provides an MFP for a unit of a selected drug is not also required to provide a 340B discount on that same drug if the MFP is lower than the 340B ceiling price (and vice versa, that the MFP does not need to be made available if the 340B ceiling price is lower). That is, these price concessions are not cumulative.

Further, CMS understands the interest in ensuring compliance with the statutory requirement to avoid duplication of the MFP and the 340B ceiling price for a selected drug. CMS also notes the interest in requiring that all Part D claims be marked as either 340B or non-340B to ensure that there is no duplication of 340B prices with the pass through of the MFP. At this time, CMS is examining options with respect to identification of 340B units in consultation with HRSA and interested parties. In addition to any policies or procedures that CMS may adopt in this regard, CMS will also work with HRSA to ensure the MFP is made available where appropriate in a nonduplicated amount to the 340B ceiling price.

Comment: A few commenters recommended CMS create accessible materials that list the MFP for a selected drug and the date the MFP applies for Medicare beneficiaries to reference to understand access to the MFP. A few commenters recommended CMS incorporate information about the MFP of a selected drug into various beneficiary outreach materials.

Response: CMS thanks these commenters for their recommendations. CMS is committed to helping Medicare beneficiaries understand access to a negotiated MFP for a selected drug during the price applicability period. CMS will publish on its website the MFP at the per unit (e.g., tablet) level for each NDC-11 associated with the selected drug. CMS will also develop accessible materials to educate Medicare beneficiaries, as well as the health care providers and other organizations that serve them, on benefits related to the Negotiation Program.

Comment: One commenter recommended CMS reduce the need for Primary Manufacturers to retain any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers for units of selected drug. The commenter recommended CMS reduce the timeframe from ten years to six years from the date of sale due to the burden and costs associated with retaining these records.

Response: CMS thanks this commenter for the recommendation. CMS believes ten years is a reasonable requirement for record retention for these sales to align with the statute of limitations period under the False Claims Act.[14]

Suggestion of Error and Corrective Actions and Compliance (Sections 40.2.3 and 40.5)

Comment: Some commenters asked CMS to consider a dispute resolution process for any disputes on claims-level data, including 340B claims. A few commenters suggested that CMS delay reimbursement during any dispute resolution process. A few commenters suggested that if CMS does not create a dispute resolution process, that CMS develop stewardship principles within the Negotiation Program, including for facilitating access to the MFP.

Response: CMS thanks these commenters for their recommendations. CMS notes that it intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to support the verification of dispensing of a selected drug to an MFP-eligible individual. CMS believes that engaging with an MTF to facilitate data transfer for eligibility purposes could minimize the potential for claims-level disputes. With respect to the Primary Manufacturer's obligation to provide access to the MFP, requirements are described in sections 40.4 and 90.2 of this revised guidance. CMS is also providing Primary Manufacturers with a corrective action process, detailed in section 40.2.3 of this revised guidance.

Comment: A few commenters asked that CMS establish a dispute resolution process that would apply to various aspects of the Negotiation Program. One commenter asked that the dispute resolution process be established prior to the September 1, 2023, deadline for publication of selected drugs.

Response: CMS thanks these commenters for their recommendations. Section 1198 of the Act prohibits administrative or judicial review of CMS' determinations of drug selection, unit determination, and the determination of MFP. CMS recognizes that Primary Manufacturers, at times, may disagree with CMS regarding certain calculations during the negotiation process. Therefore, if a Primary Manufacturer in good faith believes that CMS has made an error in the calculation of the ceiling for the selected drug or the computation of MFP across dosage forms and strengths, section 40.5 of this revised guidance notes that the Primary Manufacturer can submit a suggestion of error. Additionally, sections 40.2.3 and 100.2 of this revised guidance have been revised to provide an opportunity for corrective action in certain circumstances in which a violation of a requirement could result in a CMP being issued.

[14] 31 U.S.C. § 3731(b).

Comment: A commenter asked that CMS allow for broader stakeholder input in any dispute resolution process that is created.

Response: CMS thanks the commenter for their recommendations. After considering feedback from multiple interested parties for initial price applicability year 2026, CMS updated section 40.5 of this revised guidance to allow Primary Manufacturers the opportunity to suggest potential errors to CMS in the event that the Primary Manufacturer has a good faith belief that CMS has made an incorrect calculation. Further, CMS updated section 100.2 of this revised guidance to describe how Primary Manufacturers will have an opportunity to correct identified incompleteness or inaccuracies in certain manufacturer-submitted information in instances in which a violation of a data submission requirement could result in the imposition of a CMP. CMS will continue to evaluate those processes for future years.

Other Provisions in the Agreement (Section 40.7)

CMS solicited comment on this section, but did not receive any comments that are not otherwise addressed elsewhere (see the Medicare Drug Price Negotiation Program Agreement (Sections 40, 40.1, and 40.6) section above).

Negotiation Factors (Section 50)

Comment: Many commenters supported the use of certain cost-effectiveness measures to gain insight into the relationship between cost and effectiveness for a selected drug and its therapeutic alternative(s). Cost-effectiveness measures mentioned by commenters included Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), and Health Years in Total (HYT) and alternative methods recommended for assessing cost-effectiveness included Generalized Risk-Adjusted Cost-Effectiveness (GRACE) and Generalized Cost-Effectiveness Analysis (GCEA). Some commenters recommended convening experts to advise CMS on whether such metrics or methods are appropriate for assessing clinical benefit within the context of negotiation. Some commenters requested CMS clarify that the use of such measures is permitted when evaluating clinical benefit.

Response: CMS appreciates these commenters' responses and suggestions. CMS indicates in section 50.2 of this revised guidance that CMS will review cost-effectiveness measures and studies that use such measures for initial price applicability year 2026 to determine if such measures are permitted under section 1194(e) of the Act. CMS may use content in a study that uses a cost-effectiveness measure if it determines that the cost-effectiveness measure used is permitted in accordance with the law. A measure will not be used to adjust the initial offer if the measure does not provide information related to the negotiation factors described in section 1194(e) of the Act or is used in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than the life of an individual who is younger, nondisabled, or not terminally ill, in accordance with section 1194(e)(2) and section 1182(e) of Title XI of the Act. CMS clarifies in this revised guidance that it will not use Quality-Adjusted Life Years (QALYs) to determine any offer.

Comment: Many commenters interpreted the initial memorandum as stating a CMS decision not to use QALYs when assessing clinical benefit of a selected drug and its therapeutic alternative(s) and supported such a decision.

Response: CMS appreciates these commenters' feedback and reaffirms that QALYs will not be used in the Negotiation Program. CMS will consider studies that use QALYs only when they contain other content that is relevant and permitted under section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act.

Comment: Some commenters urged CMS not to use any metrics of cost-effectiveness or clinical effectiveness because the metric and/or the underlying data or assumptions used to develop the metric may be discriminatory. Some commenters stated that CMS should adopt a full prohibition on the use of QALYs and/or "similar measure[s]" under the relevant prohibition in the Patient Protection and Affordable Care Act.

Response: CMS reaffirms that QALYs will not be used in the Negotiation Program to adjust CMS offers. In response to feedback received on whether any measures may be permissible under section 1194(e)(2) and section 1182(e) of Title XI of the Act, CMS revised section 50.2 of this revised guidance to indicate CMS will review and consider cost-effectiveness measures and studies that use such measures for initial price applicability year 2026. However, while such measures may be reviewed, they will not be used to adjust the initial offer if the measures do not provide information related to the negotiation factors described in section 1194(e) of the Act or are prohibited under section 1194(e)(2) of the Act, or under section 1182(e) of the Act.

Comment: Regarding CMS' intent to use data that can be separated from the use of QALYs within a given study, a couple of commenters requested clarification on how CMS would separate such evidence from QALYs. A few commenters requested that CMS not consider any study referencing QALYs in determining the initial offer.

Response: Per section 1194(e)(2) of the Act, comparative clinical effectiveness research may not be used "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." CMS will not, per section 1182(e) of Title XI of the Act, use QALYs but may review the underlying data, results, or other content in studies that employ QALYs. By doing so CMS may glean important insights into the outcomes associated with the drug under consideration. For example, a study using QALYs to examine the cost-effectiveness (i.e., reviewing the cost per outcome) of drug A compared to drug B for the treatment of cardiovascular disease will describe the population of interest and quantify the outcomes. Factors in the study that do not treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or terminally ill, such as demographic information, blood pressure, cardiovascular events, and mortality before and after starting drug A versus starting drug B may provide important data to CMS about the clinical benefit of drug A when compared to drug B. Reviewing demographic information and outcomes, such as in this example, does not require CMS to review the results of the QALY calculation but may still provide important clinical information.

This approach aligns with CMS' decision to not use QALYs in the Negotiation Program while also enabling CMS to review and consider relevant information.

Comment: Many commenters requested that CMS simplify the process by which the public, including patients and caregivers, can submit information on the negotiation factors described in section 1194(e)(2) of the Act and the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW). Commenters requested additional time for submissions and clarity on the format in which information should be submitted to ensure usability for the submission of factors related to sections 1194(e)(1) and 1194(e)(2) of the Act.

Response: CMS appreciates commenters' feedback. Due to the statutory timeline of the negotiation period, including the requirement under sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act for CMS to issue an initial offer by February 1, 2024, it is not feasible to extend the timeframe for the submission of information under section 1194(e)(2) of the Act. However, as described in section 60.4 of this revised guidance, CMS will host patient-focused listening sessions that will be open to the public, including patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties, to share patient-focused input on the therapeutic alternative(s) and other section 1194(e)(2) information regarding selected drugs. These patient-focused listening sessions will occur in Fall 2023 after the section 1194(e) data submission, which will give patients and other interested parties additional time to prepare their feedback. Regarding the standardization of submissions, CMS expects a wide range of data to be appropriately submitted as part of the process and does not seek to limit the types of data submitted based on format. CMS will review submissions in alignment with sections 50 and 60 of this revised guidance.

Comment: Some commenters supported CMS' decision to open the submission of section 1194(e)(2) factors to the public. Some commenters suggested evaluating bias in information submitted or requiring a conflict of interest disclosure.

Response: CMS appreciates commenters' feedback. As described in section 50.2 of this revised guidance, CMS will consider, among other factors, the source of information, whether the study has been through peer review, as well as risk of bias during review. CMS also requires that declarative statements submitted via the Negotiations Data Elements ICR be supported by cited evidence unless the submission is a description of personal experience. This approach focuses on the merit of the information provided.

Comment: One commenter suggested requiring an executive summary of manufacturer-submitted data and another suggested requiring manufacturers to report rebates at the drug level.

Response: CMS appreciates commenters' suggestions. The comment suggesting that CMS require an executive summary of manufacturer-submitted data is out of scope for the Negotiation Program guidance and will be considered for the revised Negotiation Data Elements ICR. Regarding the comment suggesting manufacturers be required to report rebates at the drug level, CMS consulted with subject matter experts and representatives of the pharmaceutical and biotechnology industry in developing the definitions described in Appendix C of this guidance to align with statutory data collection requirements and other federal programs.

Comment: A few commenters suggested that CMS validate manufacturer data using independent data sources or suggested a third-party entity validate manufacturer data instead of CMS. One commenter recommended that CMS specify that submissions may be audited to ensure accuracy.

Response: CMS will validate manufacturer-submitted data to the extent possible, including via audit as deemed appropriate, pursuant to compliance monitoring activities under section 1196(b) of the Act.

Comment: Some commenters stated that the Negotiation Data Elements ICR included unclear expectations or data formatting inconsistent with current manufacturer approaches to tracking such data. A few commenters stated this could generate risk for the manufacturer and that a standard data format should be clarified. One commenter requested that CMS clarify that only the Primary Manufacturer is responsible for submitting data on factors described in section 1194(e)(1) of the Act.

Response: The Primary Manufacturer is responsible for providing manufacturer-submitted data described in section 1194(e)(1) of the Act and section 50.1 of this revised guidance. More information on what must be reported can be found in Appendix C of this revised guidance. Comments on formatting are out of scope for the Negotiation Program guidance and will be considered in the revised Negotiation Data Elements ICR.

Comment: A couple of commenters requested that CMS accept any information provided by a manufacturer of a selected drug even if such information is not tied to a specific statutory factor.

Response: CMS will accept information as outlined in this revised guidance and the Negotiation Data Elements ICR in accordance with statutory requirements.

Comment: One commenter requested manufacturer data submissions be provided to CMS on a rolling basis to permit adequate time to compile accurate and complete data given the relationship between inadequate submissions and CMPs. Another commenter requested sufficient time for manufacturers to evaluate requests for information and price offers from CMS before a manufacturer is determined to be noncompliant and/or enforcement actions are taken. This commenter suggested that CMS has flexibility to establish the timeframe between publication of the selected drug list (September 1, 2023 for initial price applicability year 2026) and submission of data required under section 1194(e) of the Act (stated in the initial memorandum as October 2, 2023), particularly given the resulting tax liability for failure to submit data.

Response: CMS appreciates commenters' concerns regarding deadlines. Pursuant to sections 1191(d)(5)(A) and 1194(b)(2)(A) of the Act, Primary Manufacturers must submit the manufacturer-specific data described in sections 1193(a)(4)(A) and 1194(e) of the Act to CMS by October 2, 2023 for initial price applicability year 2026. CMS will use data submitted by the Primary Manufacturer and other interested parties when developing the initial offer for a selected

drug along with CMS analyses and assessments of evidence as described in section 50.2 of this guidance. CMS is abiding by the statutory deadlines in this revised guidance.

Comment: One commenter requested that CMS clarify that consideration of manufacturer average net unit price will not trigger a future renegotiation of MFP.

Response: Renegotiation is out of scope for this revised guidance for initial price applicability year 2026 and will be addressed in future guidance or rulemaking, as appropriate.

Establishment of a Single MFP for Negotiation Purposes (Section 60.1)

Comment: Some commenters expressed concern with CMS' proposal to use a 30-day equivalent supply to apply the MFP across dosage forms and strengths, particularly for drugs with irregular intervals, topicals, and drugs taken for acute symptoms. Some commenters requested that CMS provide alternative options, consult with manufacturers on the methodology to be used for a selected drug, and/or work with interested parties to better understand how 30-day equivalent supplies are calculated for those medicines that have irregular or varied dosing schedules.

Response: CMS appreciates commenters' feedback and requests for clarity. This revised guidance provides additional detail about how CMS will use the days' supply field in PDE data to calculate 30-day equivalent supply using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) when calculating the MFP ceiling (described in section 60.2 of this revised guidance) and using the WAC ratio for initial price applicability year 2026 to apply the MFP across dosage forms and strengths (described in section 60.5 of this revised guidance). For purposes of weighting across dosage forms and strengths, CMS believes that calculating a 30-day equivalent supply, using the days' supply field, is feasible for the high-expenditure, single source Part D drugs that might be subject to negotiation for initial price applicability year 2026. As described in section 60.3.2 of this revised guidance, when comparing prices of the therapeutic alternative(s) for purposes of informing a starting price for the initial offer, CMS may use an alternative methodology for calculating a 30-day equivalent supply when appropriate.

Limitations on Offer Amount (Section 60.2)

Comment: A few commenters opposed the approach described in the initial memorandum, which these commenters asserted would result in the ceiling being applied twice. One commenter agreed with CMS that an MFP should be calculated specific to dosage forms and strengths and account for the variation in prices "specific to each dosage form and strength of the selected drug," but proposed negotiating multiple MFPs per drug by calculating the ceiling for the lowest unit of measure of a selected drug and establishing a metric from which CMS may negotiate a percent of the MFP ceiling to arrive at the published MFP per lowest unit of measure.

Response: CMS appreciates commenters' feedback. CMS disagrees that the procedure that it described in the initial memorandum would have applied the MFP ceiling twice. However, after consideration of the comments, for initial price applicability period 2026, CMS has revised section 60.2 of the guidance to use the single ceiling per 30-day equivalent supply across all

dosage forms and strengths of the selected drug. This approach aligns with the concept of negotiating an MFP for a whole selected drug across multiple dosage forms and strengths (as identified on the list of NDC-11s of the selected drug in the CMS HPMS, per section 40.2 of this revised guidance) subject to a single MFP ceiling, and then applying that MFP across dosage forms and strengths as required under section 1196(a)(2) of the Act. As discussed in the response to comments under section 60.5 below, CMS intends to monitor the practical effect of its procedures for applying the MFP across the dosage forms and strengths of the selected drug to inform its use of its section 1196(a)(2) authority for initial price applicability years after 2026.

Comment: A few commenters recommended that CMS revise the non-FAMP calculation to use the four quarters of the fiscal year, as opposed to the calendar year, to align with the Veterans Health Care Act of 1992 and reduce burden on manufacturers. Relatedly, commenters recommended that CMS develop mechanisms to account for anomalies in the non-FAMP and to permit restatements of the average non-FAMP due to data or other errors identified after the fact.

Response: Section 1194(c)(6) of the Act defines average non-FAMP to mean "the average of the non-Federal average manufacturer price... for the 4 calendar quarters of the year involved." As a result, the statutory language requires that the calendar year be used to calculate the average non-FAMP. CMS has revised the definition of non-FAMP in Appendix C to clarify that any restatements of the non-FAMP made in any applicable manufacturer non-FAMP submissions to the Department of Veterans Affairs (VA) must be reflected in the non-FAMP submitted to CMS as part of the section 1193(a)(4)(A) manufacturer data submission. Section 50.1.1 and Appendix C of this guidance discuss how manufacturers should report non-FAMP to CMS in cases where there are no data or data are insufficient to calculate non-FAMP for at least one calendar quarter of 2021.

Comment: A few commenters requested clarification as to whether the time period for determining if a selected drug is an extended or long-monopoly drug runs to the start of the applicable initial price applicability year or selected drug publication date. Commenters noted that the initial memorandum is inconsistent, applying the length of time one way when describing the initial delay request made by a biosimilar manufacturer (i.e., to the start of the initial price applicability year) and another when determining the monopoly type as well as the applicable percent specified for the purposes of establishing a ceiling (i.e., to the selected drug publication date).

Response: CMS thanks these commenters for their careful review of the initial memorandum and appreciates their flagging this inconsistency. CMS has revised section 60.2.3 of this guidance to clarify that the time period for determining whether a selected drug is an extended- or long-monopoly drug runs to the start of the applicable initial price applicability year, as specified in sections 1194(c)(4)(A) and 1194(c)(5)(A) of the Act, respectively. However, CMS notes that, as discussed in section 60.2.3 of this guidance, the definition of "extended-monopoly drug" under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030. CMS interprets this to mean that no selected drug will be considered an extended-monopoly drug for purposes of calculating the ceiling prior to initial price applicability year 2030.

Comment: A couple of commenters requested that CMS clarify whether unit refers to non-FAMP units or PDE units in the calculation of the annual non-FAMP for the dosage forms and strengths of the selected drug.

Response: CMS thanks these commenters for their careful review of the initial memorandum and appreciates the requests for clarification. CMS has revised section 60.2.3 of this guidance to clarify that PDE units will be used when averaging non-FAMP across NDC-11s. This is consistent with the use of PDE units to average NDC-9[15] non-FAMP amounts to a whole drug non-FAMP amount.

Comment: A few commenters disagreed with CMS' intent to use DIR data in calculating the "sum of the plan-specific enrollment weighted amounts" for purposes of determining the MFP ceiling. These commenters claim that the "plan specific enrollment weighted amount" is defined by reference to the Part D negotiated price, which does not include price concessions from manufacturers.

Response: Section 1194(c)(2)(A) of the Act states that the "plan-specific enrollment weighted amount" for a Part D or MA-PD plan with respect to a covered Part D drug is calculated using the negotiated price of the drug under the plan "net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan," and as such CMS plans to use DIR data, including information on manufacturer rebates and other price concessions collected through DIR reporting, in calculating the "sum of the plan-specific enrollment weighted amounts" under section 1194(c)(1)(B) of the Act.

Comment: One commenter recommended that CMS provide manufacturers with an opportunity to review and reconcile CMS' data for the MFP ceiling calculation for a selected drug. One commenter expressed concern that CMS is engaging in various conversion calculations to move from data at the NDC-11 level to the NDC-9 level to the whole drug level without providing sufficient detail to interested parties.

Response: CMS appreciates commenters' feedback. As discussed in section 60.4 of this revised guidance, CMS will provide the Primary Manufacturer information on the calculation of the statutorily-determined ceiling price. However, CMS is not able to provide manufacturers with all data used in ceiling calculations, as some of the calculations use proprietary information.

Comment: One commenter suggested that CMS should consider that the manufacturer-specific factors in section 1194(e)(1) of the Act could constitute the floor for price negotiations while the factors in section 1194(e)(2) could constitute the ceiling, keeping in mind the statutory ceiling in section 1194(c).

Response: As the commenter notes, section 1194(c) of the Act provides a specific formula for the calculation of the ceiling on the MFP for a selected drug, which is further described in section 60.2 of this guidance. The statute also requires CMS to consider the nine factors

[15] In this guidance, the NDC-9 refers to the first two segments of the NDC-11 that represent the labeler code and product portions of the NDC and indicate a drug's dosage, form, and strength regardless of the package size.

described in sections 1194(e)(1) and 1194(e)(2) when developing the initial offer. The statute does not direct CMS to use the manufacturer-submitted data or the section 1194(e)(2) data to establish a floor or ceiling, respectively, for price negotiations.

Methodology for Developing an Initial Offer (Section 60.3)

Comment: Many commenters recommended that CMS set the initial offer at or near the ceiling for all or a subset of selected drugs; for example, drugs that have provided therapeutic advancements, filled an unmet need, or otherwise demonstrated significant patient benefit; drugs under patent protection; small molecule drugs; and all drugs for initial price applicability year 2026 and for several subsequent price applicability years thereafter.

Response: CMS appreciates commenters' input. Section 1194(b)(1) of the Act instructs CMS to develop and use a consistent methodology and process for negotiations that aims to achieve agreement on the lowest MFP for each selected drug and in doing so, to consider the nine factors described in sections 1194(e)(1) and 1194(e)(2) of the Act. Offering the ceiling without a more thorough review of those statutory factors, including manufacturer-submitted data, may not achieve that objective and is inconsistent with the statutory directive.

Comment: CMS received many comments related to the identification of therapeutic alternative(s). Some commenters expressed concern regarding CMS' intent to use the price of the therapeutic alternative(s) in developing the offer starting point, including that drugs would be identified as the therapeutic alternative(s) based on cost rather than clinical appropriateness and that patients' needs will be overlooked when identifying the therapeutic alternative(s). A few commenters also noted that drugs in certain classes have few equivalent or substitutable alternatives. Some commenters were generally supportive of CMS' approach to identifying the therapeutic alternative(s), including limiting comparators to pharmaceutical alternatives, identifying therapeutic alternative(s) by indication, and considering off-label use when appropriate. However, a few commenters opposed CMS' approach to consider off-label use when identifying the therapeutic alternative(s). One commenter recommended that CMS identify no more than two comparators, one of which should be the lowest cost alternative and the other the most commonly used alternative. Another commenter stated that there is variability in how different entities define therapeutic categories, which results in different combinations of drugs in that therapeutic category. Many commenters recommended that CMS provide manufacturers, health care providers, and patients with the opportunity to participate in the selection of the therapeutic alternative(s).

Response: CMS appreciates commenters' feedback. As described in section 60.3.1 of this guidance, CMS will identify the therapeutic alternative(s) based on clinical appropriateness and consideration of various sources of evidence including clinical guidelines, peer-reviewed literature, drug compendia, and data submitted by manufacturers and the public, and not based on the cost of therapeutic alternative(s). CMS also may consult with FDA in the process of identifying other approved therapies for the same indication and with health care providers, patients or patient organizations, and academic experts to ensure that the appropriate therapeutic alternative(s) are selected. CMS expects that the negotiation offer/counteroffer exchange, as well as the negotiation meetings, will offer an opportunity for discussion about the therapeutic

alternative(s) with manufacturers. Further, as described in section 60.4 of this guidance, CMS will provide additional engagement opportunities for interested parties via manufacturer data submission-focused meetings and patient-focused listening sessions after the October 2, 2023 deadline for submission of information on the section 1194(e) data. CMS will provide additional information about these engagement opportunities at a later date.

Comment: Some commenters requested clarification as to whether generic drugs and biosimilars may be included as the therapeutic alternative(s). A few commenters opposed such inclusion because it would enable CMS to undervalue medicines. A few commenters expressed support for including generic and biosimilar therapeutic alternative(s) to establish the starting point for the initial offer.

Response: CMS appreciates commenters' feedback. As described in sections 60.3.1 and 60.3.2 of this guidance, CMS will consider the range of Part D net prices and/or ASPs of therapeutic alternative(s) for the selected drug, including prices of generic and biosimilar therapeutic alternative(s) if clinically appropriate.

Comment: Some commenters expressed support for CMS' proposal to consider the Part D net price or ASP of therapeutic alternative(s) for the selected drug as the starting point for the initial offer. A few commenters had concerns that considering Part D net prices would result in an inflated starting point and recommended CMS use the lowest net price or ASP as the starting point or the manufacturing cost and adjust based on clinical benefit. Another commenter recommended that CMS go beyond the net price of therapeutic alternative(s) to include all health system costs associated with the selected drug and its therapeutic alternative(s). One commenter recommended that if there are multiple therapeutic alternatives, CMS should use the highest-value alternative. Some commenters proposed additional options for the offer starting point, including using the MFP ceiling as the starting point or using comparative effectiveness to establish a price range or threshold for the initial offer.

Response: CMS understands concerns that using the Part D net price or ASP of a therapeutic alternative for the selected drug may result in a higher starting point; however, using net price(s) and ASP(s) of therapeutic alternative(s) enables CMS to start developing the initial offer within the context of the cost and clinical benefit of a group of drugs that treat the same disease or condition. As described in section 60.3.2 of this guidance, CMS will consider the range of Part D net prices and/or ASP(s) of therapeutic alternative(s), which may include consideration of generics and biosimilars as well as on- and off-label use (if such use is included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia). Some of the proposed alternatives for determining an offer starting point would not consider the clinical benefit provided by the selected drug relative to its therapeutic alternative(s). For example, if CMS were to use the MFP ceiling for the selected drug as the starting point, all adjustments to the starting point would be decreases, which could limit CMS' ability to adjust the starting point to recognize superior clinical benefit of the selected drug compared to therapeutic alternative(s). Rather than using manufacturing costs as a starting point, CMS will adjust the preliminary price based on manufacturer-specific data elements, including but not limited to the unit costs of production.

Comment: A couple of commenters indicated that CMS' intent to cap the offer starting point at the MFP ceiling is inconsistent with the statute. These commenters noted that the statute only requires that CMS not make an initial offer or accept a counteroffer that is above the statutory ceiling, and that limiting each step of the initial offer development process at the ceiling would lower the amount CMS could subsequently adjust based on other statutory factors (i.e., manufacturer-submitted data and clinical benefit).

Response: CMS appreciates commenters' feedback. CMS believes that the statute grants CMS flexibility to determine the amount of the initial offer, provided that the offer does not exceed the ceiling. Specifically, section 1194(b)(2)(F) of the Act requires that CMS may not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling, but does not prohibit CMS from applying the ceiling when determining the starting point of the initial offer. Further, section 1194(b)(1) of the Act instructs CMS to develop and use a consistent methodology and process for negotiations that aims to achieve agreement on the lowest MFP for each selected drug. CMS' approach of using the Part D net price or ASP of the therapeutic alternative(s), as applicable, as the starting point to determine the initial offer only if it is lower than the ceiling is consistent with this directive. As discussed in section 60.3 of this revised guidance, CMS will further adjust the starting point by the other factors specified in section 1194(e) of the Act.

Comment: CMS received many comments regarding its intent to use the Federal Supply Schedule (FSS) or Big Four price[16] as an offer starting point for selected drugs with no therapeutic alternative(s) or for selected drugs with therapeutic alternative(s) with Part D net prices and/or ASPs greater than the statutory ceiling. Some commenters disagreed with CMS' approach, noting that these prices do not reflect market prices because of certain required discounts. Other commenters were concerned that if Medicare uses these prices, it could put upward pressure on the FSS and Big Four prices, or manufacturers would be less willing to provide price concessions to the Big Four.

Response: CMS thanks these commenters for their remarks and understands the concerns raised. As discussed in section 60.3 of this revised guidance, CMS will use FSS/Big Four prices in situations where the selected drug has no therapeutic alternative(s) or the price of the therapeutic alternative(s) exceeds the ceiling. CMS believes use of FSS/Big Four prices is appropriate in these situations, as these prices are publicly available and are reflective of prices available to other federal payers.

Comment: A commenter requested that CMS limit downward adjustments related to prior Federal financial support to an amount proportional to the amount of prior Federal financial support as a share of total investment in research and development (R&D) in the selected drug.

Response: CMS appreciates these suggestions. As described in section 60.3.4 of this guidance, for each selected drug, CMS may consider each factor outlined in section 1194(e)(1) in isolation or in combination with other factors. With respect to prior Federal financial support specifically,

[16] The Big Four price is the maximum price a drug manufacturer is allowed to charge the "Big Four" federal agencies, which are the Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard. See section 8126 of title 38 of the U.S. Code. See: https://www.cbo.gov/publication/57007.

CMS will consider the extent to which the Primary Manufacturer benefited from such Federal financial support with respect to the selected drug. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

Comment: Many commenters indicated the definition of unmet medical need provided in section 60.3.3.1 of the initial memorandum was too narrow and should include situations where patients may not respond to or tolerate available treatments or disease burden remains significant. Some commenters suggested the definition should consider populations with disparities in outcomes or access. Some commenters proposed adopting the definition of unmet need from the FDA's expedited review programs. One commenter suggested looking to the National Comprehensive Cancer Network (NCCN) definition. A couple of commenters suggested looking to the framework used for New Technology Add-On Payments (NTAP). Many commenters recommended incorporating the patient perspective and/or broader societal or public health benefits when determining whether a selected drug fulfills an unmet medical need. A few commenters suggested reviewing unmet medical need across a product's lifecycle. A couple of commenters suggested reviewing unmet medical need at the time of FDA approval.

Response: CMS appreciates commenters' feedback and has reviewed the variety of definitions and frameworks suggested. After consideration of these comments, CMS revised the definition of unmet medical need to further align with section 1194(e)(2)(D) of the Act and FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" to include drugs that may have a therapeutic alternative but the existing alternative does not adequately address the condition or disease indicated (as described in section 60.3.3.1 of this revised guidance). Because the FDA guidance was issued in May 2014 and includes nonbinding recommendations, CMS will consider the guidance a reference and will consider any updates concerning unmet medical need that may be issued by FDA. CMS encourages patients and other interested parties to submit their perspective on how a selected drug meets an unmet medical need through the Negotiation Data Elements ICR submission and in the patient-focused listening sessions that will be held in Fall 2023, per revised section 60.4. More information on patient-focused listening sessions is forthcoming.

CMS also appreciates comments suggesting unmet medical need should be evaluated across a product's lifecycle. CMS will evaluate unmet medical need as of the time the section 1194(e)(2) data is submitted, which aligns with CMS' approach to reviewing manufacturer costs and data, therapeutic alternative(s), and other negotiation factors.

Comment: Many commenters supported using clinical benefit as the primary means for developing the initial offer. A few commenters stated CMS should deemphasize distribution costs when reviewing manufacturer-submitted data. A commenter suggested manufacturer-submitted data only be considered for selected drugs that provide fewer clinical benefits than the therapeutic alternative(s).

Response: CMS appreciates commenters' support for using clinical benefit to inform the initial offer. CMS is required to consider the factors described in section 1194(e) of the Act, as applicable to the selected drug, but there is flexibility to use these factors to inform the initial

offer and final offer, if applicable, in such a way as to recognize the unique characteristics of a selected drug. Regarding distribution costs, as described in section 60.3 of this guidance, CMS will adjust the starting point for the initial offer based on factors related to clinical benefit and then consider manufacturer-submitted data for additional adjustments, as appropriate. CMS also notes that the information submitted by the manufacturer and the public as well as information gathered through CMS' analysis will be considered in totality.

Comment: A few commenters suggested CMS should apply special considerations when evaluating orphan drugs or apply an upward adjustment for drugs with orphan indications, drugs that represent a significant therapeutic advance, and drugs that address an unmet medical need(s).

Response: As noted in the guidance, CMS will consider the totality of evidence when developing the initial offer. If a selected drug represents a significant therapeutic advance or addresses an unmet medical need, all other factors held constant, the initial offer for that selected drug would be higher than if this were not the case. CMS continues to explore whether there are additional actions that can be taken in the Negotiation Program to support orphan drug development, and CMS appreciates continued input from interested parties on this topic.

Comment: Many commenters requested additional detail on how negotiation factors, including those submitted by the Primary Manufacturer, would be weighted and how evidence would be evaluated and prioritized, stating additional transparency is needed. Many commenters suggested developing or adopting an existing framework for evaluating submitted information. A commenter requested CMS define "therapeutic advance."

Response: CMS appreciates commenters' feedback and recognizes the importance of balancing transparency and confidentiality in the negotiation process. CMS believes it is important to maintain flexibility when considering how each negotiation factor contributes to the initial offer and final offer, if applicable, which may be impacted by the unique characteristics of each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives. Regarding therapeutic advance, CMS will determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes for the selected drug compared to its therapeutic alternative(s) as described in section 60.3.3.1 of this revised guidance. CMS also included considerations for how evidence will be prioritized in section 50.2 of the initial memorandum and this revised guidance.

Comment: Many commenters recommended that real-world evidence,[17] information from clinical experts, and/or patient and caregiver perspectives be prioritized when reviewing negotiation factors. A few commenters suggested both qualitative and quantitative approaches be used to review negotiation factors and develop an initial offer. One commenter noted that CMS

[17] Real-world evidence is clinical evidence about the usage and potential health benefits or risks of a medical product derived from real-world data. Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. From *Framework for FDA's Real-World Evidence Program*, December 2018. See: https://www.fda.gov/media/120060/download.

should consider the limitations of real-world evidence, particularly real-world evidence based on patient registry data and the limitations of data from electronic health records and billing records.

Response: CMS agrees with commenters on the importance of real-world evidence as well as the limitations of such evidence, as with any type of data. CMS also agrees with commenters on the importance of the perspective of clinicians, patients, and caregivers. CMS included real-world evidence and consultation with clinical experts and academic researchers in the initial memorandum and, as described in section 60.4 of this revised guidance, CMS will host patient-focused listening sessions that would be open to the public, including patients, beneficiaries, caregivers, consumer and patient advocacy organizations, and other interested parties, to share patient-focused input on therapeutic alternative(s) and other section 1194(e)(2) data regarding selected drugs. CMS may also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant health outcomes of the patient taking the selected drug. As noted in the initial and revised guidance, CMS will take a qualitative perspective when reviewing a selected drug and consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality. By employing a qualitative approach to information review rather than a more formulaic quantitative approach, CMS is able to preserve flexibility in negotiation, including the ability to consider nuanced differences between different drugs that might not be captured in a more thoroughly pre-specified quantitative approach.

Comment: A few commenters noted that CMS should include the caregiver experience and equity as factors in the negotiation process. A couple of commenters requested that for specific populations, CMS relax data prioritization standards to ensure underserved and underrepresented populations are considered. One commenter recommended that CMS prioritize studies that include individuals from diverse racial and ethnic backgrounds.

Response: CMS thanks these commenters for their feedback. Health equity is the first pillar of the CMS Strategic Plan, which builds health equity into the core functions of CMS, including the Negotiation Program.[18] As noted in the initial memorandum, CMS will consider information related to a selected drug within specific populations. In this revised guidance, CMS clarified that this includes underserved and underrepresented populations, as applicable, that may be experiencing disparities in health outcomes or access to the selected drug. As noted above, CMS will also consider the caregiver perspective to the extent that input reflects directly upon the experience or relevant health outcomes of the patient taking the selected drug. This information will be collected using the Negotiation Date Elements ICR and is open to the public. All applicable negotiation factors will be considered in totality for each selected drug.

Comment: Some commenters suggested that the negotiation factors be expanded to include adherence, convenience, societal impact, caregiver burden, independence, lost wages, travel expenses, costs to patients, medical costs, value of hope, cost of side effects, and other indirect costs. One commenter recommended that CMS de-prioritize or exclude indirect health benefits and instead focus solely on health outcomes to develop the initial offer.

Response: CMS agrees that factors such as adherence and convenience (as applicable to patient experience and outcomes) are important to consider for a selected drug. CMS views such factors

[18] See: https://www.cms.gov/cms-strategic-plan.

as directly related to patient experience and as such, considers these to be included in the factors outlined in the guidance. CMS appreciates commenters' suggestions to add broader societal, economic, and public health factors to those that will be considered during negotiation. Upon reviewing commenters' suggestions for additional factors, CMS revised the guidance to include consideration of both health outcomes and other outcomes when evaluating the benefit of the selected drug and therapeutic alternative(s). Outcomes such as changes to productivity, independence, and quality of life will be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug and are permitted in accordance with section 1194(e)(2).

Comment: Some commenters recommended using Multi-Criteria Decision Analysis (MCDA) as a framework for evaluating evidence related to a selected drug and its therapeutic alternative(s).

Response: CMS appreciates this suggestion. Due to the statutory timeline, conducting a full MCDA is not feasible. CMS will consider whether the general approach used in MCDA can serve as an informative framework for evaluating evidence.

Comment: A few commenters suggested that CMS share its literature review and other materials related to the selected drug and its therapeutic alternative(s) with the manufacturer of the selected drug.

Response: Per section 1194(b)(2) of the Act and this revised guidance, CMS will provide each manufacturer of a selected drug with an initial offer and a concise justification of the factors used to develop the offer.

Comment: Many commenters stated that CMS should not decrease the initial offer based on existing patents and exclusivities provided by the FD&C Act or PHS Act and recommended the initial offer be increased in cases where a drug has existing patents and exclusivities. Many commenters are concerned that a downward adjustment based on patents and exclusivities will stifle innovation, may impact patient access, disincentivize R&D, and work against the purpose of the patent system. A few commenters believe a downward adjustment based on patents and exclusivities exceeds CMS' statutory authority. A few commenters noted that CMS' action may constitute "a taking requiring just compensation" under the Fifth Amendment's Takings Clause and stated that patents are a constitutionally protected property right.

Response: CMS appreciates commenter feedback on adjusting the initial offer price based on patents and exclusivities provided by the FD&C Act or PHS Act ("exclusivities"). The statute explicitly directs CMS to consider data on approved patents and exclusivities in its determination of the amount of the initial offer. CMS does not believe that its implementation of this statutory mandate constitutes a taking or otherwise implicates or violates the Fifth Amendment Takings Clause. CMS also notes that the example provided in the initial memorandum was intended to provide an illustrative example of how such data could be considered in developing an initial offer. However, as discussed in section 60.3.4 of this revised guidance, following further consideration of the issue, CMS has omitted the example provided in the initial memorandum. This revised guidance clarifies CMS' belief that this information will support CMS' consideration of the 1194(e)(1) and 1194(e)(2) factors described in section 60 of this revised

guidance. For instance, patents and exclusivities may inform CMS' understanding of therapeutic alternatives and other available therapy for the purposes of adjusting for clinical benefit, including consideration of whether the selected drug represents a therapeutic advance or meets an unmet medical need. More specifically, in light of exclusivities, there may be no other available therapy aside from the selected drug that adequately addresses treatment or diagnosis of a condition; consideration of such information would be relevant to CMS' consideration of the extent to which the selected drug addresses an unmet medical need for that condition.

Comment: Many commenters requested that CMS develop additional opportunities for patient, caregiver, and clinician input throughout the negotiation process, particularly to provide input on therapeutic alternative(s) to the selected drug, patient-reported outcomes, health outcomes, whether the drug fulfills an unmet medical need, weighing evidence, and benefits and impacts of the selected drug. Many commenters requested a structured, standardized means for such input to be provided such as roundtables, an advisory or stakeholder panel, listening sessions, town halls, additional meetings, or creating a patient ombudsman to engage with interested parties. A few commenters pointed to FDA's Patient-Focused Drug Development program as one that CMS can adopt or model. Some commenters requested that patients be recognized in this revised guidance as subject matter experts. Some commenters requested that patients and clinical experts be included early and throughout the negotiation process to provide input on therapeutic alternative(s) and negotiation factors such as outcomes of importance and care preferences.

Response: CMS appreciates commenters' recommendation to incorporate additional opportunities for patient, caregiver, and clinician input. In this revised guidance, patients and caregivers have been added as interested parties with whom CMS may consult. CMS will host patient-focused listening sessions that will be open to the public, including patients, beneficiaries, caregivers, consumer and patient advocacy organizations, health care providers, and other interested parties to share patient-focused input on therapeutic alternative(s) and other data on the factors in section 1194(e)(2) for a selected drug and its therapeutic alternative(s). These patient-focused listening sessions will occur in Fall 2023 after the section 1194(e) data submission, which will give patients and other interested parties additional time to prepare their feedback. CMS may draw from the principles and strategies in FDA's "Patient-Focused Drug Development – Collecting Comprehensive and Representative Patient Input" guidance when facilitating patient-focused listening sessions. Additional information is forthcoming.

Negotiation Process (Section 60.4)

Comment: Some commenters suggested that interested parties should be allowed to submit new section 1194(e) data after the October 2, 2023 initial price applicability year 2026 deadline when there is good cause. Commenters also said that not allowing new data submission until the negotiation meetings could result in an inefficient process. One commenter also mentioned that some new data may be in formats that are not conducive to meetings, such as graphs and charts.

Response: CMS recognizes the interest of manufacturers to be involved early in the negotiation process beyond the section 1194(e) data submission due on October 2, 2023. CMS also recognizes the value of current and future patient and other interested parties' input in the negotiation process as well as throughout the implementation of the Negotiation Program. CMS

revised this guidance to allow for meetings after the section 1194(e) data submission deadline of October 2, 2023, where manufacturers can provide context for their submissions, and listening sessions where patients and interested parties can provide input as CMS begins reviewing data.

First, CMS would meet with the Primary Manufacturer of each selected drug once after the October 2, 2023 deadline so that the manufacturer has an opportunity to present its section 1194(e) data submission and share its perspective. These meetings will occur in Fall 2023. Primary Manufacturers may bring materials to facilitate discussion and CMS may request any materials presented afterwards. Primary Manufacturers are limited to sharing 50 pages (or a combination of pages, slides, and/or charts totaling 50 pages) of material, in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting, anticipating that these materials may contain cross-references to other material, particularly other material already submitted to CMS. This material is meant to provide context on the Primary Manufacturer's 1194(e)(1) submission and may also be used to share any new information regarding the section 1194(e)(2) data that has been identified following the October 2nd data submission.

Second, CMS will host patient-focused listening sessions for the selected drugs that would be open to the public, including patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs. Interested parties may also use these listening sessions to orally share new information regarding the section 1194(e)(2) data that has been identified since the October 2nd deadline. These patient-focused listening sessions will occur in Fall 2023 after the section 1194(e) data submission deadline, which will give patients and other interested parties additional time to prepare their input. Additional information about these listening sessions will be shared in the future.

Manufacturers are required to provide information on the non-FAMP and information required to carry out negotiation (i.e., the section 1194(e)(1) data), by October 2, 2023 for initial price applicability year 2026. CMS expects Primary Manufacturers to submit information that is complete and accurate by this deadline. Information shared during the Primary Manufacturer meetings described above and materials shared afterwards should only contextualize the Primary Manufacturer's October 2nd section 1194(e)(1) submission; new section 1194(e)(1) data will not be considered. But, as described above, new information on section 1194(e)(2) data will be considered. Similarly, patients, beneficiaries, caregivers, consumer and patient advocacy organizations, and other interested parties may provide contextual information on their October 2nd section 1194(e)(2) data submission and/or share new section 1194(e)(2) data.

Comment: Some commenters recommended that CMS should allow negotiation meetings to happen throughout the negotiation period (i.e., between the publication of the selected drug list through the conclusion of negotiations), and not just in the situation when a manufacturer's counteroffer is rejected. A few commenters suggested specific periods during the negotiation process where CMS should hold meetings with manufacturers of selected drugs, such as after drug selection and prior to the initial offer.

Response: In response to comments requesting the opportunity to provide additional section 1194(e) data submissions to inform CMS' initial offer and negotiations after October 2, 2023, concerns about the tight timeline for data submission, and recommendations to remove any meeting caps and allow meetings throughout the negotiation period, CMS has revised this guidance to allow for manufacturer meetings and patient-focused listening sessions after the October 2, 2023 deadline. CMS would hold one meeting with the Primary Manufacturer of each selected drug to allow the Primary Manufacturer to provide context for the section 1194(e) data submission as CMS reviews the submitted data and develops its initial offer. The patient-focused listening sessions will be open to patients, beneficiaries, caregivers, consumer and patient advocacy organizations, and other interested parties and will invite attendees to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs. Manufacturer meetings and patient-focused listening sessions will occur in Fall 2023. CMS will schedule the meeting with the Primary Manufacturer once the selected drug list is published, and more information will be forthcoming from CMS regarding the patient-focused listening sessions after the selected drug list is published.

Comment: Some commenters stated that limiting negotiation meetings to a maximum of three meetings is restrictive and recommend that CMS allow for more exchanges throughout the negotiation period. One commenter asked that CMS make the meetings more transparent through recorded minutes, records of attendees, and allow any interested party to participate.

Response: The timeline for the negotiations extends from February 1, 2024, the statutory deadline for CMS to make the initial offer on a selected drug to a manufacturer, to July 31, 2024, a total of six months. The statutory deadline for the conclusion of negotiations is August 1, 2024. Up to three negotiation meetings with the manufacturer can occur. During these meetings, the Primary Manufacturer may provide context on the section 1194(e) data submission and additional relevant input on CMS' initial offer and the Primary Manufacturer's counteroffer as CMS reviews data and develops its final offer. Additional meetings (i.e., more than the maximum of three) during the negotiation period after the Primary Manufacturer's counteroffer, if applicable, are not feasible due to time constraints.

As part of the public explanation of the MFP, CMS will publish redacted information on any negotiation meetings that occur if a Primary Manufacturer's counteroffer is rejected.

As mentioned in the responses to the comments directly above, CMS is adding one meeting for each manufacturer and listening sessions for other interested parties after the data submission deadline and before CMS' initial offer is made. These meetings will allow Primary Manufacturers and other interested parties to share their perspectives as CMS reviews data and develops initial offers.

Comment: A few commenters suggested that CMS provide justifications for counteroffer responses and not just initial offers.

Response: CMS thanks these commenters for their feedback. Section 1194(b)(2)(D) of the Act requires that CMS provide the manufacturer with a written response to the manufacturer's counteroffer. CMS believes that if CMS declines the Primary Manufacturer's counteroffer and

offers a meeting, the first meeting between CMS and the Primary Manufacturer will provide an opportunity for CMS to explain its rationale for not accepting the manufacturer's counteroffer.

Comment: Some commenters asked that CMS' justification of its initial offer be meaningful and explain how CMS arrived at the offer. Commenters mentioned that the justification should include sources CMS referenced, section 1194(e) data considered and how they were weighted, therapeutic alternatives considered, interested parties consulted, and benefits and impacts of the drugs considered. One commenter asked that CMS issue a template for the initial offer justification in the final guidance.

Response: CMS thanks these commenters for their feedback and will consider the suggestion to include the information listed in the comment above when developing initial offers and concise justifications for selected drugs. Section 1194(b)(2)(B) of the Act directs CMS to provide a "concise justification" to the Primary Manufacturer when the initial offer is made. CMS will include information that helps the Primary Manufacturer understand the range of evidence and other information submitted pursuant to section 1194(e) that CMS found compelling in developing its initial offer. Because this information will be shared with the Primary Manufacturer, CMS believes the concise justification will be meaningful and provide information that will enable the manufacturer to develop its counteroffer. CMS does not plan on issuing a template for the initial offer or the concise justification but will release redacted information regarding the initial offer with the MFP explanation no later than March 1, 2025.

Comment: One commenter suggested that CMS issue a confidential report to manufacturers alongside the initial offer and concise justification. This confidential report would make manufacturers aware of section 1194(e)(2) data submitted by other interested parties and allow manufacturers to use that information in counteroffers, if applicable, and in future data submissions.

Response: CMS understands that manufacturers may benefit from awareness of section 1194(e)(2) data submitted by other interested parties during the negotiation period and that all interested parties would value receiving access to this information ahead of data submission for initial price applicability year 2027. CMS revised this guidance to state that CMS will aim to share with the Primary Manufacturer of a selected drug the section 1194(e)(2) data received from other interested parties during the negotiation period when feasible. These data will be appropriately redacted and will not include proprietary information, protected health information (PHI) / personally identifiable information (PII), or information that is protected from disclosure under other applicable law. If an MFP is reached during the negotiation period, CMS will issue the public explanation of the MFP no later than March 1, 2025. As part of this public explanation, CMS will share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. This redacted information will not contain any proprietary data, as described in section 40.2.1 of this guidance, PHI / PII, or other information that is protected from disclosure under other applicable law. However, as described in section 40.2.1, if a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary and will not redact it in the public explanation.

Comment: A few commenters asked CMS to commit to responding to counteroffers within 30 days of receipt. Commenters also recommended CMS give manufacturers at least 30 days to review and comment on CMS' response to counteroffers and asked CMS to consider these comments before setting the MFP.

Response: Section 60.4.3 of this revised guidance reaffirms the statement from section 60.4.4 of the initial memorandum that CMS will provide a written response to the manufacturer's counteroffer, if applicable, no later than 30 days after the receipt of the manufacturer's counteroffer. CMS made minor revisions to section 60.4.3 to clarify that CMS will respond in writing no later than 30 days after receipt of a manufacturer's counteroffer regardless of the nature of the response.

CMS declines to revise the guidance to allow manufacturers 30 days to review and comment on CMS' response to counteroffers. If a manufacturer's counteroffer is rejected, negotiation meetings with the Primary Manufacturer and CMS will span from approximately April 1, 2024 to June 28, 2024. This period exceeds 30 days and will give Primary Manufacturers the opportunity to comment on CMS' response to the counteroffer in negotiation meetings.

If applicable, CMS will issue a "Notification of Final Maximum Fair Price Offer" no later than July 15, 2024, and require Primary Manufacturers to respond to this final offer by July 31, 2024. Although this turnaround is less than 30 days, it will come at the end of approximately six months of negotiations (February 2024-July 2024) where there will have been ample opportunity for the Primary Manufacturer to review the initial offer, respond in writing via a counteroffer, and consider the discussions that occurred within the context of up to three negotiation meetings, including any additional proposals for an MFP made by CMS.

Comment: A couple of commenters recommended CMS establish a definition for "meeting" and consider adopting a policy similar to the 2017 FDA guidance "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products: Guidance for Industry," which details meeting criteria and has definitions for different tiers of meetings.

Response: CMS thanks these commenters for their feedback. CMS has updated the description of meeting criteria in section 60.4.3 of this guidance to provide more information on the number of permitted attendees, length of each meeting, meeting scope, and meeting logistics. CMS believes that the meetings as part of the negotiation process under the Negotiation Program have a different purpose than FDA's formal meetings under the user fee agreements and therefore has taken a different approach when defining its meeting standards.

Comment: One commenter suggested CMS allow Secondary Manufacturers to participate in the negotiation process, including negotiation meetings.

Response: CMS thanks this commenter for this feedback. As described in section 60.4.3 of this memorandum, negotiation meetings would be attended solely by representatives of both the Primary Manufacturer and of CMS. CMS will defer to the Primary Manufacturer to identify its preferred representatives it plans to have attend any negotiation meetings.

Comment: One commenter stated that if CMS and a manufacturer engage in bona fide negotiations that result in no agreement, then the MFP should be set at the ceiling.

Response: CMS believes that this suggestion does not align with the statute. The statute envisions a period of negotiations that are expected to result in an agreement between the two parties on MFP by a certain date. The statute does not provide a "default" option if negotiations are not successful. This recommendation is inconsistent with the framework of the statute and would undermine the purpose of the Negotiation Program if manufacturers are assured the ceiling as long as they engage in good faith efforts to negotiate on an MFP.

Comment: One commenter suggested CMS consider issuing further guidance in the future on how data will be used in the negotiation process to determine MFP, as this may promote reaching agreements during negotiations.

Response: CMS will consider the totality of evidence throughout the negotiation period, including when developing the initial offer, reviewing a possible counteroffer, and participating in negotiation meetings when applicable. CMS will leverage the negotiation data described in section 50 to inform the methodology described in section 60.3 and the negotiation process described in section 60.4. Additional documents, such as the various ICRs associated with the Negotiation Program and this revised guidance, provide more detail related to the negotiation process and how data will be used.[19]

Application of the MFP Across Dosage Forms and Strengths (Section 60.5)

Comment: Some commenters indicated that CMS' methodology for calculating the MFP and applying it across dosage forms and strengths is overcomplicated, arbitrary, and inconsistent with the statute. Some commenters also opposed CMS' proposal to use a 30-day equivalent supply to apply the MFP across dosage forms and strengths. A few commenters expressed support for CMS' approach to applying the MFP across dosage forms and strengths, including to new NDAs, BLAs, and NDCs.

Response: CMS appreciates commenters' feedback. The statute requires a single price negotiation to agree upon an MFP for a selected drug, and contemplates that CMS will establish "procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug." As such, CMS will identify one MFP for a selected drug, which it will base on the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths.

Comment: Some commenters opposed CMS' proposed approach to apply the MFP across dosage forms and strengths by calculating a WAC ratio that represents the WAC of a given dosage form and strength compared to the WAC of the whole drug. A few commenters indicated

[19] For ICRs related to the Negotiation Program, see: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

that WAC is a flawed measure because it does not reflect discounts and that it changes over time. A couple of commenters recommended that CMS consider other price metrics such as AMP.

Response: CMS appreciates commenters' concerns regarding the use of the published WAC. For initial price applicability year 2026, CMS will use the WAC ratio to apply the MFP across dosage forms and strengths of a selected drug and will monitor changes to WAC relative to other pricing data, as well as shifts in utilization across dosage forms and strengths. CMS appreciates the commenters' recommendation to use AMP, but is concerned that using AMP prices in place of WAC could potentially disclose manufacturers' proprietary data. CMS recognizes there may be other ways to apply the MFP to dosage forms and strengths and will monitor whether this policy serves the intent of the Negotiation Program. As noted throughout this revised guidance, the policies described for the Negotiation Program are for initial price applicability year 2026, and CMS may consider additional policies for future years of the Negotiation Program.

Comment: Some commenters requested that for purposes of transparency and clarity, CMS provide to manufacturers the data used in MFP calculations, include example calculations in guidance, and publish a decision-making framework.

Response: CMS agrees with commenters about the importance of clarity and transparency in MFP calculations. CMS believes the discussion in sections 60.2 and 60.5 of this revised guidance sufficiently describes the methodologies CMS will use to calculate a single ceiling for a selected drug and to apply the single MFP negotiated for a selected drug across dosage forms and strengths of the selected drug (as identified at the NDC-11 level on the list of NDC-11s of the selected drug in the CMS HPMS, per section 40.2 of this revised guidance) and as such, this revised guidance does not include example calculations. However, as discussed in section 60.4 of this revised guidance, CMS will provide to the Primary Manufacturer information on the calculation of the statutorily-determined ceiling and application of a single MFP across dosage forms and strengths. However, CMS is not able to provide manufacturers with all data used in MFP calculations, as some of the calculations use proprietary pricing information.

Publication of the MFP (Section 60.6)

Comment: Some commenters recommended that the public explanation of the MFP provide details on the negotiation process, what data were considered, and how they were weighted when arriving at the final MFP. Commenters also suggested CMS share information on methodologies, therapeutic alternatives, outcomes metrics, interested parties engaged, and comparative effectiveness research considered. Several commenters also requested CMS explain how patient experience data and real-world evidence were used and how unmet need was factored in when developing the MFP. Commenters also broadly recommended that the public explanation of the MFP be transparent and detailed.

Response: CMS believes that all interested parties should have a transparent understanding of the process and rationale that CMS and the Primary Manufacturer of the selected drug used when negotiating the MFP and how that reasoning evolved over time. In addition to the data elements required by law to be submitted by the Primary Manufacturer regarding the selected drug, CMS expects robust participation by interested parties in submitting information and participating in

the patient-focused listening sessions for the selected drugs. As required under section 1195(a)(1) of the Act, CMS will publish the public explanation of the MFP for each selected drug no later than March 1, 2025. The public explanation, as described in the revised section 60.6.1 of this guidance, will include a narrative explanation of the negotiation process that occurred with that manufacturer and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable, in alignment with the confidentiality policy described in section 40.2. CMS will also strive to share the section 1194(e)(2) data submitted by the public with the Primary Manufacturer of a selected drug during the negotiation period. This data will be redacted as per the confidentiality standards described in section 40.2 and will not include proprietary information, PHI / PII, or other information that is protected from disclosure under other applicable law. CMS thanks these commenters for their feedback.

Comment: A few commenters recommended CMS make the publication of the MFP and explanation clear, accessible, and transparently available for the public. These comments mention ensuring the information is easy to read, easy to access, and developed in a consumer-friendly format. A couple of commenters suggested CMS include information on how beneficiaries can access the MFP and provide a process to follow if the MFP is not honored. One commenter suggested a webpage that provides the brand name (proprietary name) and generic name (non-proprietary name) for each selected drug where there is an MFP, MFPs for all dosage forms, and the dates the prices are in effect. Another commenter suggested providing a summary in the public explanation so that patients can understand the negotiation process and what to expect when procuring a medication with an MFP.

Response: CMS thanks these commenters for their feedback regarding the publication of the MFPs of the selected drugs and explanations of those MFPs. As described in section 60.6 of this revised guidance, CMS will publish the following on the CMS website by September 1, 2024 for all initial price applicability year 2026 selected drugs where an MFP was agreed upon: the selected drug, the initial price applicability year, and the MFP pricing file for that selected drug. The MFP file will contain the MFP as applied to each selected drug at the single MFP for a 30-day equivalent supply, NDC-9 per unit price, and NDC-11 per package price and will be updated annually to show the inflation-adjusted MFP for the selected drug. CMS will also publish on the CMS website: when a drug is no longer a selected drug and the reason for that change, and situations in which an MFP between a Primary Manufacturer and CMS is not agreed upon. No later than March 1, 2025, CMS will publish the public explanation of the MFP for each initial price applicability year 2026 selected drug. CMS is committed to providing accessible educational materials to beneficiaries, and the pharmacies, mail order services and other dispensers that serve them, about the MFPs for selected drugs and how they can report a violation if they do not believe that they were able to access the MFP for a selected drug.

Comment: Some commenters urged CMS to provide as much information as legally possible when issuing the public explanation of the MFP. These commenters stated that a high level of transparency will garner confidence that the negotiated MFP is the lowest price that CMS could obtain. One commenter asked that CMS release at minimum non-FAMP, R&D costs and recoupment, and unit costs of production, and distribution. Other commenters stated that the only

information that should be withheld from public explanations are R&D costs, unit costs of production, and certain net pricing information.

Response: CMS thanks these commenters for their feedback. CMS is committed to a negotiation process that is transparent and respects confidentiality of proprietary information. CMS appreciates the need to balance both transparency in the negotiation process to assure interested parties and the public that the negotiations were conducted in a fair manner, and that CMS attempted to achieve agreement on the lowest possible MFP for the selected price for Medicare beneficiaries, with the need to maintain the confidentiality of certain information, including manufacturers' proprietary data. As part of the public explanation of the MFP, CMS will release a narrative explanation of the negotiation process and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. All information that CMS publishes as part of the public explanation and any other public documents related to the MFP and negotiation process will abide by the confidentiality policy described in section 40.2 and redact proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law.

Comment: One commenter expressed concern that CMS' definition of R&D costs and recoupment was too narrow and suggested that CMS broaden its scope for R&D costs for failed and abandoned products to include all products in the relevant disease state, not just products with the same active moiety / active ingredient as the selected drug. The commenter also felt that CMS' intent to compare R&D costs and global, net revenue reported resulted in an unfair comparison, as global revenue may include products and indications without FDA approval and be supported by separate clinical trials. The commenter asked, if CMS does not revise the definitions, that CMS explain the calculation methodology and inputs in all publications regarding the negotiation process, especially the public explanation of the MFP. The commenter also said CMS should note where its definitions of concepts may differ from others.

Response: CMS thanks this commenter for this feedback. CMS believes that for the purpose of the Negotiation Program, the definition of R&D costs is sufficiently broad, as reflected in the additional revisions and clarifications made to Appendix C, as noted below. To the extent R&D costs and recoupment inform the final MFP for a selected drug, this information and how it was used will be described, with appropriate redactions for proprietary information, as part of the public explanation of the MFP. For more information on CMS' consideration of R&D costs and recoupment definitions, please see the comment and response section for Appendix C.

Comment: One commenter recommended that CMS carefully evaluate what information to include in the public explanation of the MFP and consider whether requests not to disclose some information are to protect business interests or to undermine a transparent process.

Response: CMS thanks the commenter for this feedback. CMS is committed to a transparent process and will follow the confidentiality policy as described in section 40.2 in this revised guidance when developing the public explanation of the MFP. As discussed earlier in this section, as part of the public explanation, CMS will publish redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS' publication of this information will abide by the confidentiality

policy described in section 40.2 and redact proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law.

Comment: One commenter suggested CMS limit its disclosure of information in the public explanation of the MFP to only information that is already public information.

Response: CMS thanks the commenter for this feedback. CMS is committed to a transparent process and will follow the confidentiality policy as described in section 40.2 in this revised guidance when developing the public explanation of the MFP.

Comment: Some commenters recommended that CMS allow manufacturers to review the explanation for the MFP before it is published so that manufacturers can provide comments and raise concerns about inadvertent disclosure of confidential information.

Response: CMS recognizes the interests of the manufacturers in making sure that certain data they provided to CMS for the negotiation process remain confidential. The statute does not require disclosure of the explanations of the MFP provided to manufacturers before the explanations are made public. Additionally, section 40.2 of this revised guidance describes the information from manufacturers that CMS will consider and maintain as confidential. CMS does not intend to share the explanations of the MFP with manufacturers before releasing the explanations to the public.

Comment: Many commenters suggested that CMS publish the explanation of MFP for all selected drugs with an MFP before the statutorily defined deadline for initial price applicability year 2026 of March 1, 2025. Some commenters recommended that CMS release the explanations along with the first set of MFPs for selected drugs on September 1, 2024, while other commenters did not specify a date. Commenters suggested an earlier publication so that interested parties can review the explanation and understand CMS' negotiation process ahead of submitting section 1194(e) data for initial price applicability year 2027 by the March 1, 2025 deadline.

Response: CMS thanks these commenters for their feedback. According to the statute, the public explanation of the MFP must be published no later than March 1, 2025 for initial price applicability year 2026 selected drugs. CMS understands commenters' interest in reviewing these public explanations in advance of the deadline for manufacturers of drugs selected for negotiation for initial price applicability year 2027 to submit their information, and will strive to release the public explanation of the MFP as soon as practicable. CMS notes that the policies for initial price applicability year 2027 will be shared in future guidance, including whether the policies adopted for section 1194(e)(2) submissions for initial price applicability year 2026 will apply in a similar manner for initial price applicability year 2027, and if so, when those submissions would be due.

Comment: One commenter recommended that, in addition to the public explanation of the MFP, CMS issue a summary report for all negotiated drugs in initial price applicability year 2026 and provide data on various negotiation outcomes. The commenter also suggested a summary report

and using SSR Health and IQVIA data may avoid confidentiality concerns around data from manufacturers.

Response: CMS thanks these commenters for their feedback. In response to comments, CMS revised section 60.6.1 of this guidance so that the public explanation of the MFP now includes a narrative explanation of the negotiation process and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS' publication of this information will abide by the confidentiality policy described in section 40.2 and redact any proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law. CMS believes that, with these revisions, the public explanation of the MFP will be sufficiently comprehensive and will achieve the goals suggested by the commenter.

Comment: One commenter recommended that CMS publish the NDCs along with the list of MFPs for selected drugs. One commenter recommended that when CMS releases MFPs and associated data, the list should include selected drug active moieties / active ingredients, their respective NDCs, and unit-level MFPs in a structured and machine-readable format. The commenter also suggested CMS provide additional context on how CMS will use NDC-9s to calculate the unit-level MFPs for every dosage form and strength of the selected drug and how the structure and formatting of the MFP file release will be affected by FDA's proposed rule on the NDC-12 format.[20]

Response: CMS thanks the commenter for this recommendation. CMS will publish by September 1, 2024 the MFP for each drug selected for initial price applicability year 2026 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file (which will contain the MFP as applied to each selected drug at the single MFP for a 30-day equivalent supply, NDC-9 per unit price, and NDC-11 per package price and will be updated annually to show the inflation-adjusted MFP for the selected drug), and the explanation for the MFP (published at a later date). The MFP file will be machine-readable and in a .CSV format. While CMS understands FDA has issued a proposed rule regarding changes to the format of FDA-issued NDCs, CMS does not believe that this proposed rule is relevant to the Negotiation Program or the establishment of the MFP for initial price applicability year 2026 because the policy, if finalized as proposed, would take effect five years after the final rule is published.

Exclusion from the Negotiation Process Based on Generic or Biosimilar Availability (Section 60.7) and Establishment of MFPs After the Negotiation Deadline (Section 60.8)

CMS solicited comment on these sections, but did not receive any comments that are not otherwise addressed elsewhere (see the "Bona Fide Marketing" section below).

[20] Revising the National Drug Code Format and Drug Label Barcode Requirements, July 25, 2022, available at https://www.federalregister.gov/documents/2022/07/25/2022-15414/revising-the-national-drug-code-format-and-drug-label-barcode-requirements

Removal from the Selected Drug List (Section 70)

Comment: Some commenters recommended CMS not apply the MFP to a selected drug if CMS determines that a generic drug or biosimilar is approved and marketed after the negotiation period but before the start of initial price applicability year 2026. One commenter recommended that CMS replace a selected drug that is removed from the selected drug list. One commenter recommended that, if a generic drug or biosimilar competitor of a selected drug receives FDA approval or licensure before the end of the negotiation period, CMS should establish a grace period after the negotiation period ends (e.g., 30 days) for CMS to consider whether that generic or biosimilar has been bona fide marketed. One commenter asserted that section 1192(e) of the Act requires CMS to remove a selected drug from the selected drug list if a generic drug or biosimilar is approved and marketed before the start of the applicable initial price applicability year.

Response: CMS thanks these commenters for the recommendations. Section 1192(c), not section 1192(e) of the Act, governs the circumstances under which a selected drug would be removed from the selected drug list after the date that that list is published. Section 1192(c) of the Act requires a selected drug that is included on the selected drug list to remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines the statutory criteria in section 1192(c) are met unless CMS makes the determination before or during the negotiation period that a generic drug or biosimilar product for the selected drug is approved or licensed and is marketed. CMS interprets this requirement such that a drug included on the selected drug list published for initial price applicability year 2026 will remain a selected drug for initial price applicability year 2026 unless CMS determines on or before August 1, 2024 that a generic drug or biosimilar product for the selected drug has been approved for marketing by the FDA, and that bona fide marketing exists for the generic drug or biosimilar product. If CMS determines between August 2, 2024 through March 31, 2026 that bona fide marketing exists for the generic drug or biosimilar, the selected drug would cease to be a selected drug after 2026, and no MFP would apply for 2027.

MFP-Eligible Individuals (Section 80)

Comment: One commenter recommended CMS clarify whether an MFP-eligible individual that is enrolled in Part D can receive a selected drug at the MFP if it is paid under Part B. The commenter also requested clarification that the MFP must be made available to an individual with Part D coverage, even if they choose not to use their insurance. One commenter asked CMS to detail how it will ensure access to an MFP for individuals seeking to obtain a selected drug under Part B or Part C. A couple of commenters recommended that CMS clarify that the MFP for initial price applicability year 2026 only applies when the beneficiary receives a selected drug under Part D and that the MFP does not apply when the beneficiary is administered a selected drug under Part B. One commenter stated that the definition of MFP-eligible individual includes an individual enrolled in a Medicare Advantage (MA) Plan who is furnished or administered the selected drug for which payment may be made under Part B.

Response: CMS thanks these commenters for their recommendations. CMS has clarified in section 80 of the guidance that for initial price applicability year 2026, an MFP for a selected

drug must be provided to a Medicare beneficiary who uses their Part D plan (including an MA-PD plan under Medicare Part C or an Employer Group Waiver Plan, but not a plan that receives the Retiree Drug Subsidy) if Part D coverage is provided under such plan for such selected drug. For initial price applicability year 2026, the MFP is not required to be made available to a Medicare beneficiary who uses other sources of prescription drug coverage, prescription drug discount cards, or cash. CMS has made conforming changes throughout this revised guidance to clarify the scope of the requirement to provide access to the MFP for initial price applicability year 2026. For initial price applicability year 2026, CMS does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to MFP eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan.

Bona Fide Marketing (Sections 30.1, 60.7, 70, and 90.4)

Comment: Several commenters supported CMS' proposal to determine whether bona fide marketing exists for a generic or biosimilar to (1) determine whether a drug should be selected as a qualifying single source drug, (2) determine whether a selected drug should be deselected, and (3) monitor in cases where a drug is not selected or after it has been deselected to ensure that bona fide marketing is still occurring. These commenters agreed with this approach to ensure that the presence in the market of a generic drug means that there is meaningful competition. Other commenters said that such monitoring is warranted given manufacturers' past market behavior, and identified certain market-limiting agreements that some brand name manufacturers have entered into with generic drug manufacturers to limit the supply of the generic drug and thus inhibit competition. The commenters maintained that such arrangements justify CMS' proposal to determine whether bona fide marketing of a generic or biosimilar is actually occurring. Some commenters suggested that CMS require that manufacturers attest that they have not entered into any agreements that would limit the market share of the generic or biosimilar products, either implicitly or explicitly. One commenter also suggested that CMS require manufacturers submit all agreements provided to the Federal Trade Commission (FTC).

Response: CMS appreciates the support for its reading of the statute to contemplate a determination by the agency that a generic drug or biosimilar is being marketed on a bona fide basis as part of drug selection, deselection, and monitoring of the Negotiation Program. CMS agrees with these commenters that manufacturers' past behavior warrants CMS review on an ongoing basis as to whether a generic drug or biosimilar is being bona fide marketed. Absent this review, a generic drug or biosimilar manufacturer could launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the MFP should no longer apply. This result would be inconsistent with the text of the statute as well as its purpose, which is to lower drug prices for Medicare through either negotiation or price competition. Consistent with this statutory purpose, section 1192(e)(1) of the Act requires that a generic drug or biosimilar "is … marketed" in order for a drug or biological product to be excluded from the definition of a qualifying single source drug, and section 1192(c)(1) likewise requires that a generic or biosimilar "is marketed" in order for a selected drug to be deselected. This terminology demonstrates that Congress contemplated that a generic or biosimilar must have a continuing presence on the market in order to affect CMS' determination whether a drug should be selected as a qualifying single source drug or whether a

selected drug should be deselected. Manufacturers are welcome and encouraged to provide information to CMS about the market for generic drugs or biosimilars for the selected drug.

Comment: Many commenters stated CMS lacks statutory authority to define "marketed" for purposes of selected drug eligibility under the statute, including sections 1192(e)(1), 1192(e)(2)(B), and 1192(c) of the Act[21] differently from the first market date reported by the manufacturer to the Medicare Part D Drug Inflation Rebate Program. Further, these commenters stated that CMS lacks statutory authority to address "bona fide marketing" to implement the statutory requirement of determining if a generic or biosimilar is "approved and marketed" or "licensed and marketed" under sections 1192(c) and (e) of the Act. These commenters also asserted that CMS lacks statutory authority to review product utilization or assess "robust and meaningful competition" as part of a determination of whether a generic or biosimilar is "marketed." In addition, these commenters stated that "marketing" is already a term defined in the pharmaceutical industry, including by FDA and CMS, noting that in Appendix C of the initial memorandum, marketing is defined as the "introduction or delivery for introduction into interstate commerce of a drug product." These commenters stated that any review of "marketing" for purposes of drug selection under section 1192(e) of the Act or deselection under section 1192(c) of the Act must be based on the first "market date." One commenter stated that the IRA is not intended to review market performance across an arbitrary period of time but rather whether a generic or biosimilar is marketed at the point in time of CMS' determination of drug selection. Additionally, some commenters suggested that CMS lacks statutory authority to monitor marketing after a drug/biological is determined ineligible for selection or removed from the selected drug list.

Other commenters suggested that CMS clarify the term "bona fide marketing" and its application to the Biosimilar Delay special rule and drug selection and deselection.

Response: Section 1192 of the Act requires CMS to make a determination whether a generic drug or biosimilar "is marketed" in order to determine whether a listed drug / reference product should be selected as a qualifying single source drug or whether a selected drug should be deselected. Congress purposefully used different terminology in section 1192 than it did in section 1860D-14B of the Act, which established the new Medicare Part D Drug Inflation Rebate Program. In the latter provision, Congress referred to the date that a drug is "first marketed." The absence of similar terminology in section 1192 demonstrates that, for purposes of the Negotiation Program, Congress contemplated that a generic drug or biosimilar would have a continuing presence on the market in order to affect the status of a listed drug / reference product.

Consistent with the purpose of the statute to lower prices for Medicare through negotiation or price competition, the statute contemplates that, in making this determination, CMS would consider whether meaningful competition exists on an ongoing basis between a listed drug or

[21] These determinations include whether a drug/biologic is eligible as a qualifying single source drug under section 30.1 of this guidance and whether a selected drug should be removed under sections 60.7 and 70 of this guidance because either (1) the listed drug has an approved generic drug (under section 505(j) of the Federal Food, Drug, & Cosmetic Act) or (2) the reference product has a licensed biosimilar (under section 351(k) of the Public Health Service Act) that is marketed pursuant to that approval or license.

reference product and a generic drug or biosimilar. This determination requires more than solely token or de minimis availability of the products. For example, CMS is aware of situations in which a manufacturer of a brand name drug or biologic has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar, where the generic drug manufacturer agrees to limit production or distribution of the generic version of the drug, such that only a nominal quantity of product is allowed to enter the market. The result is a lack of meaningful price competition, and in that circumstance the generic drug or biosimilar is not "marketed" within the meaning of that term as it is used in the IRA.

Given the Negotiation Program is targeted at single source drugs and biologics that have been on the market for some time, for which no generic drug or biosimilar competition currently exists, the statutory directive would not be met if a qualifying single source drug were to avoid selection or be removed from the selected drug list where generic drug or biosimilar availability is limited by the Primary Manufacturer. It is consistent with the purpose of the statute to remove the MFP for a selected drug only when there is evidence that the selected drug or biological product is subject to meaningful competition. For example, Section 1192(e)(2)(A) of the statute provides that an "authorized generic" drug or biosimilar product "shall be treated as the same qualifying single source drug." Although an authorized generic may appear to be competing with the reference drug, authorized generics are typically marketed by the brand name drug company or another company with the brand company's permission, meaning that the relationship between the brand drug and its authorized generic is not meaningful competition in the way envisioned by Congress.

Whether such competition exists between a listed drug or reference product and a generic drug or biosimilar will depend on the totality of circumstances in existence at the time that CMS performs its function of making the determination whether a generic is being marketed. Accordingly, CMS maintains the approach in this guidance of determining if the manufacturer of the generic/biosimilar is engaged in bona fide marketing of the generic/biosimilar.

For a discussion of CMS' approach to the Biosimilar Delay rule, which under section 1192(f)(1)(A) requires CMS to make the statutory determination that there is a "high likelihood" that a biosimilar "will be licensed and marketed" within the relevant statutory time frame, see section 30.3.1 of this revised guidance.

Comment: Some commenters stated CMS lacks statutory authority to establish metrics of "sufficient quantities" and "market share" to assess bona fide marketing. These same commenters suggested these terms are vague and represent arbitrary requirements. A few commenters suggested specific thresholds that CMS could use to determine if meaningful competition exists. For example, one commenter suggested pulling a threshold from literature on competitive generic markets (which the commenter suggested is at least half of the market for small molecule drugs and at least 25 percent for biosimilars) and based on standardized prescriptions (e.g., a 30-day Part D supply) to estimate the generic drug penetration relative to the total volume of products dispensed in Medicare. Specifically, the commenter suggested the calculation of the number of standardized prescriptions dispensed for the generic product divided by the number of standardized prescriptions dispensed for the selected drug aggregated across all dosage forms and strengths, plus the number of standardized prescriptions dispensed for the

generic/biosimilar. Another commenter suggested a generic/biosimilar was effectively marketed when its market share is within a standard deviation of the mean for a given period of time since market entry and/or if its market share is at or above the mean of uptake at the point in time of CMS review regarding selection or deselection of the product.

One commenter requested CMS carefully consider what bar might be too high for a sufficient market share if certain factors of a market share are out of a manufacturer's control and limit competition, for example, this commenter said certain rebates can limit competitive entry.

Response: The statute requires CMS to determine whether a generic drug or biosimilar has been approved or licensed and is marketed pursuant to such approval or licensure for which the selected drug is the listed drug / reference product. Consistent with the purpose of the statute to lower prices for Medicare through negotiation or price competition, the statute contemplates that, in making this determination, CMS would consider whether meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar. This determination requires more than solely token or de minimis availability of the products. However, CMS agrees with the commenter than CMS will not set a single specific numeric threshold for meaningful generic drug or biosimilar competition for selected drugs because CMS does not believe there is one specified threshold that would appropriately capture meaningful competition in the market for every selected drug. As described below, CMS will review multiple data sources to inform its determination whether a generic drug or biosimilar is being marketed on a meaningful basis.

CMS clarified in this revised guidance that these data sources will be reviewed holistically to determine if meaningful competition exists in the market for purposes of: (1) the identification of qualifying single source drugs for initial price applicability year 2026 (see section 30.1), (2) removal from the selected drug list before or during negotiation or after an MFP is in effect (see section 70), and (3) monitoring whether a manufacturer of a generic or biosimilar is engaged in bona fide marketing of a drug/biologic determined ineligible as a qualifying single source drug as described in section 30.1 of this guidance or removed from selection as described in section 70 of this guidance because the selected drug was the listed drug or reference biologic for a generic or biosimilar (see section 90.4). Manufacturers can provide evidence to CMS regarding the market for an approved generic drug or biosimilar that references its drug(s) to inform CMS' monitoring for bona fide marketing after a drug is not selected or after deselection.

Comment: Some commenters expressed concern regarding the time difference between the actual date of marketing and the date of CMS' determination of bona fide marketing using PDE data because of the time lag for sales to be captured in PDE data. One commenter suggested that a 12-month review period is arbitrary and CMS failed to explain why this period was selected to establish if a generic/biosimilar is marketed. Another commenter stated that the initial six months of PDE data after market entry reflect a limited uptake because Part D plan sponsors add the drug to their formulary at the 180-day CMS deadline for Part D formulary inclusion, or not at all, and additionally there is a gradual transition for product uptake by providers and patients. Another commenter stated that CMS was relying on the indicator that shows slowest generic drug uptake by relying on PDE data.

Response: CMS thanks these commenters for their feedback regarding the timing of data review. CMS chose to review data over this 12-month time period for initial price applicability year 2026 because it believes that this time range will provide a sufficient window of opportunity to demonstrate whether a generic drug or biosimilar is marketed on a continuing basis while still allowing for sufficient time for that data to inform the selected drug list published on September 1, 2023 in accordance with section 1192(a) of the Act.

While CMS appreciates commenters' concerns regarding the time lag between a generic drug's availability and the ability to detect it in PDE data resulting from filled Part D prescriptions, CMS understands that generally this timing lag is relatively short as Part D plans are instructed to submit original PDEs to CMS within 30 days following the date the claim is received or date of service (whichever is greater)[22] and the average turnaround time to date of submission is fewer days.

Under Medicare Part D rules, 42 C.F.R. § 423.120(b)(5)(iv) permits immediate substitution of a generic drug for a brand name drug on a Part D formulary, and section 1860D-4(b)(3)(I)(ii) of the Act permits removal of a selected drug if permitted by § 423.120(b)(5)(iv) (or any successor regulation). CMS expects that Part D plans would immediately substitute a generic version of the selected drug for the brand version of the selected drug. In addition, Part D sponsors may add new generic drugs and biosimilars to their formularies at any time. Thus, the Part D rules allow for relatively quick formulary substitution of generic drugs for selected drugs and the addition of generic drug and biosimilar versions of selected drugs such that both should be evident in the PDE data relatively quickly.

Nonetheless, to address commenters' concerns about the implications of any lags in timing of data used and its implications on drug selection, CMS will also review AMP[23] data at the time of the initial qualifying single source drug determination under section 30.1 of this revised guidance, any subsequent removal from selection under sections 60.7 and 70 of this revised guidance, and when monitoring whether a manufacturer of a generic drug or biosimilar is engaged in bona fide marketing of a drug/biologic determined ineligible as a qualifying single source drug as described in section 30.1 of this guidance or removed from selection as described in section 70 of this guidance because the selected drug was the listed drug or reference biologic for a generic drug or biosimilar under section 90.4 of this revised guidance. AMP data may capture sales transactions in the supply chain in situations when use of the generic drugs in Part D plans has not yet become evident in the PDE data. A drug's AMP units (which represent manufacturer sales to retail pharmacies and wholesalers that distribute to retail community

[22] Timely Submission of Prescription Drug (PDE) Event Records and Resolution of Rejected PDEs, Centers for Medicare & Medicaid Services, October 6, 2011, available at: https://www.hhs.gov/guidance/document/revision-previous-guidance-titled-timely-submission-prescription-drug-event-pde-records.

[23] See definition at Section 1927(k)(1) of the Act. Average Manufacturer Price (AMP) is the average price paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturers. AMP was established under the Omnibus Budget Reconciliation Act of 1990 for the Medicaid Drug Rebate Program and is calculated using manufacturer sales transaction data, which include cash discounts, volume discounts, and other reductions in the actual price paid to the manufacturer. CMS receives AMP data from manufacturers that have an agreement with the Secretary of HHS as specified under Section 1927(a)(1) for all Medicaid-covered outpatient drugs on a monthly and quarterly basis, as well as data on the number of units sold by the manufacturer during those time periods.

pharmacies) are reported monthly to CMS as part of a manufacturer's reporting responsibilities under the Medicaid Drug Rebate Program. PDE data and AMP data will be reviewable once the generic drug is listed in the FDA Orange Book (using at least one dosage form and strength of the selected drug as the listed drug) or the biosimilar is listed in the FDA Purple Book (using at least one dosage form and strength of the selected drug as the reference product).

Comment: A few commenters requested CMS include other data sources in addition to PDE data, such as data from NADAC, IQVIA, and DailyMed data; determinations of national market share; presence at distributors and in group purchasing organization (GPO) contracts; and presence on formularies, to determine the presence of a marketed generic or biosimilar for the selection and/or deselection of a drug or biologic. One commenter requested that CMS permit manufacturers to certify the status of the marketing of generic drugs and biosimilars and determine this marketing status on an ongoing basis.

Response: CMS thanks these commenters for these suggestions of additional sources that may include useful information to demonstrate bona fide marketing of a generic drug or biosimilar. The determination whether a generic drug or biosimilar is being bona fide marketed on an ongoing basis is a totality-of-the-circumstances inquiry that will not necessarily turn on any one source of data. Manufacturers of selected drugs can provide evidence to CMS regarding the market for the generic drug or biosimilar versions of their selected drug(s) to inform CMS' monitoring for bona fide marketing before drug selections are made, or after deselection. In addition to also reviewing AMP data, given commenters' suggestions to include additional examples of such other data that may be used, CMS clarified in sections 70 and 90.4 of this guidance (with application to sections 30.1 and 60.7 by way of cross-reference to the discussion of bona fide marketing), that CMS will use multiple sources, including but not limited to, the examples as described in sections 70 and 90.4 of this revised guidance to determine if bona fide marketing exists of the generic drug or biosimilar under review. This monitoring will ensure that drugs and biologicals ineligible for selection or removed from selection are subject to competition from generic drugs and biologicals that are marketed on a meaningful basis. CMS retains the right to consider other data in monitoring if manufacturers of the applicable generic drug or biosimilar continue to engage in bona fide marketing once a selected drug is deselected.

Comment: A few commenters encouraged CMS to monitor for manufacturing and/or marketing arrangements that intend to limit generic competition. One commenter suggested that a drug or biologic should remain eligible as a selected drug, so long as the drug or biologic otherwise qualifies, in the presence of limited distribution agreements. Another commenter suggested CMS publish arrangements that CMS views as limiting competition as a component of monitoring bona fide marketing. A couple of commenters stated that monitoring of market competition is not within CMS' authority and cited FTC and FDA regulatory frameworks to address biosimilar and generic competition.

Response: CMS thanks these commenters for these suggestions. CMS believes that limited-distribution agreements can in fact limit the supply of an available generic drug. CMS reiterates that, for the purposes of the Negotiation Program, the statute instructs CMS to make a determination whether a generic drug or biosimilar "is marketed," which requires a determination whether the generic drug or biosimilar has a continuing presence on the market.

Congress used this language in furtherance of the purpose of the Negotiation Program, which is to lower costs for Medicare through negotiation or price competition. The statute accordingly contemplates that CMS' determination will turn on a finding whether meaningful market competition for such given generic drug or biosimilar biological product exists. While these market-limiting agreements may make CMS aware of a limitation on meaningful market competition, these agreements do not necessarily inform the agency whether such a limitation is manifesting itself in the marketplace. For this reason, CMS intends to monitor actual conditions in the marketplace through PDE and AMP data. However, as commenters suggest, CMS may consult with FTC to identify the types of agreements or arrangements that limit competition. FDA does not receive agreements of this type in the normal course of its operations.

Comment: One commenter asked what action might result if CMS determines through monitoring that a generic drug/biosimilar manufacturer is not engaging in bona fide marketing after CMS determined that there was an applicable generic drug/biosimilar for which the manufacturer was engaged in bona fide marketing.

Response: If the reason for disqualification as a qualifying single source drug is removed, the drug/biologic could be eligible for negotiation in a future price applicability year.

Comment: One commenter requested CMS evaluate whether its monitoring approach accurately captures true competition and whether any specific types of drug marketing/distribution agreements limit generic competition and include in this review the impact on payers, providers and insurers. A few commenters generally expressed concerns about potential impacts they suggested that the Negotiation Program might have on generic drug markets, which they suggested could broadly include reducing the impact to a manufacturer of being the first filer for generics, promoting pricing via negotiation in lieu of market competition, or deterring generic competition and increasing drug pricing costs to payers in certain drug market segments.

Response: CMS thanks these commenters for their input and will keep these comments in mind as CMS implements the Negotiation Program and monitors for bona fide marketing over time.

Monitoring Compliance and Civil Monetary Penalties (Sections 90.1 and 100)

Comment: Many commenters requested additional details regarding the scope and amount of the CMPs, detailed procedures for determining violations and imposing fines, and a review and appeal process for determinations of noncompliance prior to the imposition of CMPs and initiation of the procedures described in section 1128A of the Act. Additionally, some commenters suggested CMS undertake notice and comment rulemaking to provide the process steps and requirements of involved parties prior to imposing any CMPs, and a few commenters requested that CMS use a single notice and comment rulemaking process to capture all instances of CMP triggers under the IRA. A few commenters instructed CMS to look to examples of CMP application in other CMS programs, including Medicare Advantage and the HHS Office of the Inspector General (HHS OIG), when establishing its procedures for the Negotiation Program. A couple of commenters suggested that the dollar amount required by the IRA for a CMP requires rulemaking under the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution. A few commenters requested a delay in the implementation of CMPs until rulemaking occurs.

Response: CMS appreciates the concern for ensuring that administration of CMPs under section 1197 of the IRA and in accordance with the requirements of section 1128A of the Act is achieved via defined procedures, and appreciates the suggestions offered by commenters. In this revised guidance, CMS has provided additional information about compliance violations that may result in CMPs being issued; the notification process surrounding compliance violations, including reminders, warnings, Notices of Potential Noncompliance, and formal CMP Notifications; and has provided a series of informative example scenarios on the scope and calculation of CMPs when applicable. CMS has also added detail to the CMP Notification process, following the requirements of section 1128A of the Act. CMS directs commenters to section 100 of this guidance for additional information. CMS reviewed examples of CMP processes in other CMS programs to develop the procedures outlined in this guidance. The amounts of CMPs are defined in section 1197 of the IRA and will be applied accordingly. CMS defines the start date and end dates for calculating violations in section 100.2 of this revised guidance.

Sections 11001(c) and 11002(c) of the IRA provide that the Secretary "shall implement" the Negotiation Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." Thus, the initial memorandum is not subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute. Section 1197 of the Act indicates violations that warrant a CMP. This guidance is consistent with the statutory requirement to use program guidance to implement the Negotiation Program for 2026, 2027, and 2028 and to impose certain penalties for violations of the Negotiation Program.

Comment: Some commenters requested that CMS share information with the Primary Manufacturer in advance of the notice of imposition of a CMP and permit the Primary Manufacturer to cure the violation for which a CMP could be imposed. Some commenters also requested a reasonable time period be specified for this cure period and a process be provided to appeal a finding of noncompliance, including as a means to safeguard against a perceived or actual legal or factual error of CMS.

Response: CMS has added in this revised guidance additional details about how Primary Manufacturers will have an opportunity for corrective action in applicable circumstances. For example, CMS revised section 100.2 of this revised guidance to clarify that CMS may request additional information to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. In addition, CMS will issue a written reminder of the impending deadline for submission of information to include a warning of potential liability for a CMP upon failure to comply with the deadline.

Comment: A few commenters expressed support for the IRA's inclusion of CMPs to support the negotiation of the MFP.

Response: CMS thanks these commenters for their feedback.

Comment: Some commenters raised concerns regarding the application of CMPs to Primary Manufacturers due to the actions of a Secondary Manufacturer that does not provide data

required under section 1194(e)(1) of the Act or the action of other third parties, including pharmacies and providers, that do not provide access to the MFP for MFP-eligible individuals. A few commenters requested CMS limit the imposition of CMPs to only a Primary Manufacturers' actions, or alternatively, refrain from enforcement of the CMP on a Primary Manufacturer for a third party's actions in initial price applicability year 2026. One commenter suggested a Primary Manufacturer be able to raise a defense against a CMP when the violation at issue was committed by a Secondary Manufacturer. A few other commenters supported monitoring and imposition of CMPs on third parties via the Primary Manufacturer, and one commenter encouraged CMS to monitor Secondary Manufacturers directly.

Response: CMS appreciates commenters' feedback regarding the imposition of a CMP on the Primary Manufacturer based on the actions of a Secondary Manufacturer or other third party. Per section 40 of this revised guidance, a Secondary Manufacturer is defined as either (1) a manufacturer listed in an NDA or BLA for the selected drug or (2) an entity that has entered into an agreement with the Primary Manufacturer to market the selected drug. A Secondary Manufacturer will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meet these criteria. As such, a Primary Manufacturer may be required to request data from a Secondary Manufacturer including non-FAMP, current unit costs of production and distribution, and certain market data elements. As described in section 1193 of the Act (described in section 40 of this revised guidance) and included in the Manufacturer Agreement, the Primary Manufacturer is also responsible for ensuring access to the MFP for MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that dispense the selected drug to an MFP-eligible individual. Because CMS is entering into the Agreement with the Primary Manufacturer, it is the Primary Manufacturer that will be responsible for adhering to the terms of the Agreement. CMS believes the Primary Manufacturer, based on its arrangements with Secondary Manufacturer(s), can reasonably ensure that the Primary Manufacturer can comply with its Negotiation Program obligations with regards to data submission and ensuring the availability of the MFP for the selected drug sold by a Secondary Manufacturer(s). CMS is not aware of circumstances where a Secondary Manufacturer can operate without a formal arrangement of the Primary Manufacturer, through which the Primary Manufacturer can ensure compliance by the Secondary Manufacturer.

As is clarified in section 100 of this revised guidance, CMS will provide an opportunity for corrective action in certain instances of potential violation prior to imposing CMPs, which may provide Primary Manufacturers an opportunity to mitigate noncompliance related to Secondary Manufacturers in applicable situations.

Comment: One commenter requested CMS identify a pathway by which third parties could provide information regarding potential violations to CMS for investigation, while another commenter suggested an online form and toll-free phone number be established for consumer complaints on MFP availability.

Response: CMS appreciates commenters' feedback. CMS will establish a dedicated telephone line and/or e-mail inbox for interested parties to report any perceived MFP availability violations. Section 90.1 provides additional information regarding monitoring of manufacturer compliance. CMS anticipates providing more information on public monitoring in the future.

Comment: Several commenters requested CMS provide information about how CMS will interpret the term "knowingly" with regard to knowingly providing false information under section 100.3 of this guidance and as applicable to violations of the Agreement under section 100.2 of this guidance. Some commenters requested that CMS interpret "knowingly" based on a plain meaning of the term or uses by other CMS programs, OIG and the False Claims Act, while others requested CMS require "actual knowledge" of the act or omission.

Response: CMS appreciates these comments. After considering the comments received, CMS has adopted a standard for "knowingly" within the context of the Negotiation Program that conforms with the HHS OIG definition at 42 C.F.R. § 1003.110. Specifically, "knowingly" is interpreted to mean that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required. CMS adopts this standard for "knowingly" in section 100.3 of this revised guidance for purposes of whether a manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) of the Act for the Small Biotech Exception and whether any Biosimilar Manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Act for the Biosimilar Delay, as provided in section 1197(d) of the Act.

In applying CMPs, CMS intends to use discretion such that CMPs are reserved for instances of substantive noncompliance. These violations do not necessarily require the violation to be "knowing." Based on statutory requirements, CMS has clarified in section 100.2 that CMS maintains the authority to issue CMPs for substantive violations of the Agreement even in cases that violations are not "knowing."

Comment: Several commenters raised concerns that the detailed and numerous Primary Manufacturer data submission requirements under the Agreement will result in violations of compliance unintended by the Primary Manufacturer unless CMS allows for Primary Manufacturers to submit data based on a reasonable assumption of the IRA statutory data requirements.

Response: CMS appreciates commenters' feedback regarding the perceived potential for CMP liability based on unintended noncompliance with data submission requirements as set forth in section 1194(e)(1) and section 50 and Appendix C of the initial memorandum. As previously noted, CMS clarified in section 100 of this revised guidance that CMS will provide manufacturers with an opportunity, via the Notice of Potential Noncompliance, for corrective action in certain instances of potential violation prior to determining whether to impose a CMP. CMS has also provided responses regarding data submissions within the responses to Appendix C comments, including revisions to Appendix C definitions in response to commenters' requests for clarifications (e.g., unit type for non-FAMP, patents to be included). CMS also directs commenters to the 30-day notice for public comment on the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW), which incorporates revisions to instructions in response to comments CMS received in response to the 60-day notice for public comment. CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the Act or otherwise use reasonable

assumptions in lieu of the definitions in Appendix C of this revised guidance. Submitted data must align with the instructions in CMS' Negotiation Data Elements ICR and the definitions in Appendix C of this guidance to ensure that the data submitted by Primary Manufacturers are based on consistent definitions and scope.

Part D Formulary Inclusion of Selected Drugs (Section 110)

Comment: Many commenters expressed support for requiring selected drugs to be included on Part D formularies. Several other commenters noted that the IRA does not detail how selected drugs should be included on formularies; therefore, CMS should confirm plan formulary flexibilities for selected drugs. A few commenters also requested CMS clarify when the formulary inclusion requirement would not apply, such as when a selected drug is excluded from negotiation because of the introduction of a generic or biosimilar competitor. Additionally, a couple of commenters expressed concern that mandating inclusion of selected drugs on Part D formularies—without establishing guardrails to ensure beneficiary access—could create perverse incentives because plans could place selected drugs on less favorable tiers compared to non-selected drugs. Finally, a couple of commenters requested CMS clarify that it will not require that Part D formularies include every dosage form and strength of a selected drug, noting that plans could comply with the IRA if only one dosage form and strength of the selected drug is included. One commenter stated Congress did not intend that every dosage form and strength of a selected drug be included on formularies.

Response: CMS appreciates commenters' feedback and agrees with commenters about the importance of ensuring meaningful beneficiary access to selected drugs and their MFPs and ensuring that plans do not engage in gaming behavior. CMS shares concerns that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. CMS expects Part D sponsors to provide their enrollees with meaningful access to selected drugs and will use its comprehensive formulary review process to assess any practices that may undermine beneficiary access to selected drugs, as discussed in section 110 of this guidance. CMS maintains a robust, clinical formulary review process to ensure that all Part D plan formularies comply with statutory and regulatory requirements, including the requirement under section 1860D-11(e)(2)(D)(i) of the Act that CMS may only approve a Part D plan if it "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Further, if CMS identifies that Part D sponsors are not providing beneficiaries with meaningful access to selected drugs, CMS may consider implementing new requirements for future contract years. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs when clinically appropriate while allowing CMS to monitor practices that may undermine enrollee access to selected drugs and inform further action, as necessary.

Section 1860-D-4(b)(3)(I) of the Act requires Part D plan formularies to include each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP is in effect with respect to the year. Accordingly, all dosage forms and strengths of the selected drug that

constitute a covered Part D drug and for which the MFP is in effect must be included on formulary. In response to the comments requesting clarification on when the formulary inclusion requirement would cease to apply, CMS refers readers to section 70 of this revised guidance, which, in accordance with section 1192(c) of the Act, details when a selected drug will cease to be a selected drug because CMS determines that a generic or biosimilar competitor to the selected drug has been approved or licensed and marketed pursuant to such approval or licensure. CMS notes that, as specified by section 1860D-4(b)(3)(I)(ii) of the Act, nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under 42 C.F.R. § 423.120(b)(5)(iv) (or any successor regulation).

Comment: A couple of commenters stated CMS should require selected drugs to be placed on lower (preferred) formulary tiers, noting that this would reduce out-of-pocket costs for beneficiaries. A couple of commenters recommended CMS ensure parity between selected drugs and non-selected drugs, such as requiring plans to cover selected drugs on the most favorable tier as any brand name drug in the therapeutic class. One commenter stated CMS should require plans to place selected drugs on lower or equivalent tiers as their competitors. A few commenters indicated that selected drugs should be placed on formulary tiers with copayments rather than coinsurance to help beneficiaries plan for their drug expenses. One of these commenters added CMS should prohibit plans from placing selected drugs on tiers that require coinsurance. Finally, one commenter recommended CMS use the specialty tier cost threshold to determine tier placement of selected drugs. Specifically, selected drugs with monthly costs less than the specialty tier threshold could be placed on the lowest generic tier and selected drugs with monthly costs greater than the threshold could be placed on higher copayment tiers.

Response: CMS appreciates commenters' feedback. For contract year 2026, CMS is not implementing explicit tier placement requirements for selected drugs, but section 110 of this revised guidance indicates how CMS will use its formulary review process to assess potentially concerning review findings. CMS generally expects that Medicare beneficiaries taking selected drugs will benefit from the lower negotiated MFPs. While CMS understands that not all selected drugs and drug classes will present Part D sponsors and their Pharmacy & Therapeutics (P&T) Committees with the same formulary considerations and might not warrant the same formulary placement in all situations, CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs. To help ensure that beneficiaries have meaningful access to selected drugs and consistent with the agency's statutory obligation to monitor plan compliance with all applicable formulary requirements, CMS will use its formulary review process to assess any instances where Part D sponsors place selected drugs on non-preferred tiers or where a selected drug is placed on a higher tier than non-selected drugs in the same class. As discussed in section 110 of this revised guidance, as part of the annual bid review process, CMS will expect Part D sponsors to provide CMS with a reasonable justification to support the submitted plan design that includes any such practices. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). As CMS reviews Part D plan formularies to ensure they comply with statutory and regulatory

requirements, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, CMS will only approve a Part D plan bid submitted by a Part D plan sponsor if CMS does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs through tier placement in a clinically appropriate manner, while allowing CMS to monitor practices that may undermine beneficiary access to selected drugs and inform new requirements for future contract years.

Comment: Many commenters expressed concern that plans will use utilization management not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs that may be associated with higher rebates. Therefore, commenters suggested CMS should limit or prohibit utilization management for selected drugs. A few commenters asserted that maintaining the ability to use utilization management will best ensure that plans can negotiate effectively with interested parties to lower prescription drug costs.

Response: CMS appreciates commenters' feedback. For contract year 2026, CMS is not implementing explicit utilization management requirements for selected drugs, but section 110 of this revised guidance indicates how CMS will use its formulary review process to assess potentially concerning review findings. CMS shares the commenters' concerns that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. To help ensure that beneficiaries have meaningful access to selected drugs and consistent with the agency's statutory obligation to monitor plan compliance with all applicable utilization management requirements, CMS will use its formulary review process to assess any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy) or where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class. As discussed in section 110 of this guidance, as part of the annual bid review process, CMS will expect Part D sponsors to provide CMS with a reasonable justification to support the submitted plan design that includes any such practices. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS reviews all Part D plan formularies to ensure they comply with statutory and regulatory requirements and, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, will only approve a Part D plan bid submitted by a Part D plan sponsor if CMS does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs through utilization management in a clinically appropriate manner, while allowing CMS to monitor practices that may undermine beneficiary access to selected drugs and inform new requirements for future contract years.

Comment: Many commenters expressed concern that price negotiation, combined with changes in interested party liability from Part D redesign, will have significant impacts on the structure of Part D and could negatively impact patient access to medicines. These commenters recommended CMS monitor plan formularies and the extent to which plans are using utilization management and tiering for selected drugs. Some commenters also recommended CMS update rules and guidance around plan coverage decisions and create safeguards to ensure patient access to a selected drug.

Response: CMS thanks these commenters for sharing their concerns regarding patient access to selected drugs. CMS agrees with commenters about the importance of beneficiaries having meaningful access to selected drugs. As such, as discussed in section 110 of this guidance and consistent with the agency's statutory obligation to monitor plan compliance with all applicable formulary requirements, CMS will use its formulary review process to assess (1) any instances where Part D sponsors place selected drugs on non-preferred tiers, (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class, (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy), or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class. As CMS reviews Part D plan formularies to ensure they comply with statutory and regulatory requirements, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, CMS will only approve a Part D plan if it does not find that the design of the plan and its benefits (including any formulary and tiered cost-sharing structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. While CMS is not implementing additional tier placement or utilization management requirements for selected drugs for contract year 2026, if CMS identifies that Part D sponsors are not providing beneficiaries with meaningful access to selected drugs, CMS may consider implementing new requirements for future contract years to ensure that Part D sponsors are not undermining beneficiary access to selected drugs.

Application of Medicare Part B and D Prescription Drug Inflation Rebate Programs to Selected Drugs (Section 120)

Comment: A few commenters stated that selected drugs should not be subject to inflation rebates. These commenters pointed to the Part B inflation rebate calculation in statute to assert that Congress did not intend for rebates to apply to selected drugs.

Response: The statute provides that the inflation rebates apply to selected drugs.[24] Specifically, the rebate calculation specified in section 1847A(i)(3)(A)(ii)(l) of the Act references section 1847A(b)(1)(B) of the Act, which includes payment for selected drugs. That is, there is no statutory exemption from inflation rebates for selected drugs. Note that CMS intends to issue final guidance relating to the Part B and Part D inflation rebates later in 2023.

Comment: Commenters requested clarification regarding the application of inflation rebates to selected drugs. One commenter asked CMS to clarify how MFPs will be factored into the inflation rebate calculations for selected drugs under the Part B and Part D programs. Another

[24] See sections 1847A(i) and 1860D-14B of the Act.

commenter urged CMS to issue guidance to ensure that the Negotiation Program and Part B Inflation Rebate Program do not have an interactive effect, and that inflation rebates should only apply when the manufacturer has increased its price.

Response: Section 120 of this guidance clarifies that the MFP for a selected drug is not included in the AMP for the selected drug and thus will not affect the Part D inflation rebate calculation.[25] CMS will provide additional information about how Part B inflation rebates apply to selected drugs in future guidance.

Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

Comment: Some commenters stated that the proposed framework for CMS' data collection and corresponding definitions to capture information required in sections 1194(e)(1) and (2) of the Act lacks the flexibility necessary to accommodate unique characteristics of different drugs/products that will be reviewed through the Negotiation Program. These commenters requested CMS rescind the proposed definitions and permit manufacturers to provide statutorily required data submissions based on reasonable assumptions along with a justification of such assumptions when interpreting the applicable IRA statutory requirements. Some commenters stated that because of the assumptions inherent in responding to a data request, CMS must use notice-and-comment rulemaking to provide information about required data. A few commenters raised concerns about differences between the definitions proposed in the initial memorandum and other pharmaceutical industry and/or government reporting requirements with related terms, and some commenters included specific term examples of these situations (included in other comments below). A couple of commenters expressed broad support for the definitions in Appendix C. Additionally, some commenters requested CMS allow manufacturers to provide supplemental data without text limits. Another commenter requested CMS establish a uniform starting point across data collections and not require data prior to this point because it could unfairly penalize manufacturers for previous pricing practices and data collection before the IRA went into effect.

Response: CMS thanks these commenters for articulating the considerations they will need to address when preparing to conform data submissions to the definitions provided in Appendix C of this guidance. CMS consulted with subject matter experts and federal agencies regarding the terms defined in this guidance. As already discussed herein, CMS engaged (and continues to engage) with interested parties through various platforms since passage of the IRA in August 2022. CMS has considered recommendations and suggestions in revising the definitions included in Appendix C of this guidance, which serve as the basis for the information to be collected under sections 1194(e)(1) and (2) of the Act. CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the Act or otherwise use reasonable assumptions. CMS believes it is important that data submissions reflect the application of consistent standards and definitions to permit appropriate consideration of such data, timely execution of the negotiation process, and enforcement actions, as warranted. As such, data submitted in response to this revised guidance must be based on consistent definitions and scope, as reflected in Appendix C of this revised guidance. CMS appreciates the resources required to meet these submission requirements. On

[25] See section 1927(k)(1)(B)(i)(VI) of the Act.

March 21, 2023, CMS released the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW) to detail the specific data that CMS is requesting for purposes of implementing the negotiation process to determine the MFP. The comment period in response to the 60-day notice closed on May 22, 2023. CMS is releasing a revised version of the Negotiation Data Elements ICR on June 30, 2023, and the 30-day comment period will close on July 31, 2023. The revised ICR is available here: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847. Comments must be submitted through www.regulations.gov.

Additionally, as explained in response to comments received regarding CMS' statutory authority to issue program instruction, sections 11001(c) and 11002(c) of the IRA state that CMS "shall implement" the Negotiation Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance"; thus, this revised guidance and corresponding data collection requirements are not subject to the notice-and-comment requirements of the Administrative Procedure Act or the Medicare statute. However, CMS is following requirements pursuant to the Paperwork Reduction Act of 1995 for information collection requests related to the administration of the Negotiation Program.

Comment: A few commenters asked for clarification on the requested data elements related to R&D costs. Some commenters expressed concern that CMS' definition of R&D costs is too narrow and excludes relevant costs such as those related to acquisition, ongoing studies or monitoring of a drug, and costs related to investments in technology that may apply to multiple drugs. One commenter recommended CMS exclude from the definition of R&D costs post-marketing clinical trials that were not completed and limit consideration of spending on abandoned and failed projects to those that were conducted within a narrower timeframe. One commenter expressed concern that the 8.1 percent capital rate specified in the guidance is too low. A few commenters stated CMS' approach for calculating recoupment of R&D costs by comparing global net lifetime revenue for the selected drug with R&D costs attributable to FDA-approved indications of the selected drug is imprecise or flawed and disadvantages the manufacturer.

Response: CMS thanks these commenters for their feedback. After consideration of the comments on this guidance and the Negotiation Data Elements ICR, CMS has revised Appendix C to consolidate several R&D cost categories. Specifically, as revised, the category "Post-Investigational New Drug (IND) Application Costs" includes costs for completed, FDA-required post-marketing trials, which were previously in their own category. The category "All Other R&D Direct Costs" includes costs associated with post-marketing trials that were not completed or were conducted for the purposes of marketing claims, which were previously in their own category. In addition, CMS revised the guidance to require reporting of acquisition costs as part of R&D costs rather than market data and revenue and sales volume data. CMS also revised the definition of basic pre-clinical research costs to clarify that the relevant time period for reporting such costs begins on the later of the date of initial discovery or the date the Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug. This revision was made to clarify that CMS does not expect the Primary Manufacturer to submit R&D costs for the time period prior to its acquisition of the rights to the selected drug.

Acknowledging that not all costs are mutually exclusive among products and that manufacturer investments can include failed drug candidates, CMS believes that for the purpose of the Negotiation Program, the definition of R&D costs is sufficiently broad. As required in section 1194(e)(1)(A), CMS must consider R&D "costs of the manufacturer related to the [selected] drug." Expanding the definition of such costs to include failures of products with different active moieties / active ingredients or mechanisms of action or in different therapeutic classes or other non-specific innovation-related costs goes beyond considering costs related to the R&D of the selected drug and does not provide a clear accounting of drug-specific R&D expenditures. In defining R&D costs, CMS considered a multitude of sources including government reports, literature searches, the FDA website, and discussions with experts. The definition is intended to be sufficiently broad to accommodate differences in accounting policies and cost allocations across different manufacturers. Manufacturers should submit additional R&D costs not included in other R&D definitions as part of "All Other R&D Direct Costs", as applicable. The 8.1 percent capital rate is consistent with assumptions used by the Congressional Budget Office in an April 2021 study on R&D in the pharmaceutical industry.[26]

CMS appreciates commenters sharing their concerns regarding comparisons of global, lifetime net revenue for the selected drug with R&D costs attributable to FDA-approved indications of the selected drug. CMS understands that R&D occurs globally and, as stated in the Negotiation Data Elements ICR instructions, the Primary Manufacturer must report R&D costs incurred in other countries that are related to the FDA-approved indication of a selected drug. As noted in the ICR and Appendix C of this revised guidance, R&D costs exclude costs associated with applying for and receiving foreign regulatory approvals. In response to commenters' concerns, CMS has revised Appendix C of this guidance, as well as the ICR, to clarify that CMS will consider both a Primary Manufacturer's global and also U.S. revenue when determining whether to adjust the preliminary price based on manufacturer-submitted data. Further, to align reporting of U.S. revenue with global total lifetime net revenue, CMS has (1) eliminated reporting of quarterly gross U.S. revenue and (2) replaced reporting of quarterly net revenue for the selected drug with U.S. lifetime net revenue for the selected drug.

Comment: Some commenters recommended CMS remove federal tax credits from the definition of prior Federal financial support and limit consideration of prior Federal financial support to only products with a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government agency. One commenter recommended that prior Federal financial support exclude indirect federal funding (e.g., provision of funding to a third party which then provides funding to the manufacturer). One commenter suggested including tax credits provided under the Orphan Drug Act and similar subsidies in addition to grants and contracts. Another commenter recommended CMS use broad definitions for "preclinical" and "novel discovery" to capture prior Federal financial support that occurs before a manufacturer acquires a viable drug product.

Response: CMS thanks these commenters for their feedback. CMS disagrees that tax credits should be excluded from the definition of prior Federal financial support. The federal government supports drug research through tax incentives. The statute does not require that CMS

[26] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," April 2021, available at https://www.cbo.gov/publication/57126.

only consider direct expenditures in prior Federal financial support or only government interest patents. CMS believes that the definition of prior Federal financial support appropriately captures industry and/or government standards in a manner that is consistent with the statutory requirements to use such information.

Comment: Several commenters raised concerns about challenges with obtaining requested information about current unit costs of production and distribution at the drug-specific level, which they stated is inconsistent with reporting requirements of other governmental bodies such as the SEC. One commenter recommended CMS allow manufacturers to use reasonable assumptions based on existing audited financial reports submitted to the SEC and/or generally accepted accounting principles. One commenter noted that it may not be able to obtain some of these data from Secondary Manufacturers. One commenter recommended CMS include channel fees in its definition of distribution costs. Several commenters recommended CMS allow manufacturers discretion to include production and distribution costs that are available to them and provide a narrative rationale for any factors they are not able to include.

Response: CMS appreciates commenters' concerns and feedback. In response to comments, CMS revised Appendix C to note that costs should be determined and reported in accordance with generally accepted accounting principles. CMS believes the Primary Manufacturer, based on its arrangements with Secondary Manufacturer(s), can reasonably ensure that the Primary Manufacturer can comply with its negotiation program obligations with regarding to data submission and ensuring the availability of MFP for selected drug sold by Secondary Manufacturer(s). CMS notes that because the agreement is between CMS and the Primary Manufacturer, it is the Primary Manufacturer's responsibility to submit certain data that will serve as the basis for offers and counteroffers. CMS declines to explicitly include channel fees in its definition of costs of distribution and notes that the definition generally refers to all (direct and allocation of indirect) costs related to packaging, labeling, and shipping operating costs for facilities and transportation. CMS refers commenters to the Negotiation Data Elements ICR for information about submitting explanations of various calculations, including unit production and distribution costs. Finally, CMS notes that the definitions of unit costs of production and distribution are intended to be sufficiently broad to account for various costs associated with producing and distributing drugs or biological products.

Comment: One commenter noted that manufacturers define kits differently than the National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards that are referenced in Appendix C. This commenter recommended including the definition to avoid confusion.

Response: This revised guidance includes a footnote to provide clarification with respect to the definition of kits to be clear that CMS is adopting the NCPDP definition for kits.

Comment: Some commenters disagreed with the scope of patent and exclusivity information that CMS proposed to collect and recommended CMS clarify and narrow the scope of these reporting requirements to, for example, include only U.S. patents and applications directly related to the Primary Manufacturer and/or selected drug. Some commenters also disagreed with the patent-related definitions adopted by CMS. A few commenters requested clarity with respect to certain terms used in this section, including the meaning of patents "linked to" or "relating to"

the selected drug. One commenter recommended removing required reporting of reference product exclusivity for biologics, stating that FDA only makes this determination if there is a regulatory necessity (as opposed to at the time of approval). A few commenters also recommended CMS obtain information about approved patent applications and marketing applications from FDA resources such as the Orange Book and Purple Book and that manufacturers be allowed to reference those sources in their submissions to CMS to reduce burden. One commenter recommended CMS align its terminology and standards with other federal laws and regulations such as those of FDA.

Response: CMS thanks these commenters for their suggestions. In drafting the Patents, Exclusivities, and Approvals section of Appendix C and the Negotiation Data Elements ICR, CMS consulted with the United States Patent and Trademark Office (USPTO) and reviewed the FD&C Act and FDA regulations. After consideration of the comments, CMS has revised Appendix C of this guidance to remove certain definitions and provide additional information about the types of patents and patent applications that CMS considers to be "related to" the selected drug. While CMS understands that certain patent information is submitted to other agencies and is publicly available in the FDA Orange and Purple Books, section 1194(e)(1)(D) of the Act requires that manufacturers submit patent information to CMS. Although some of the requested data may be publicly available, CMS may not be able to ensure that such data are complete or up-to-date. Further, other information required by section 1194(e)(1)(D) of the Act, for example, information about pending patent applications, may not be publicly available. CMS understands that FDA has not made a determination of first licensure for each 351(a) biological product included in the Purple Book and that the absence of a date of first licensure in the Purple Book does not mean that a biological product on the list is not, or was not, eligible for the periods of exclusivity described under the PHS Act. CMS expects that the Primary Manufacturer will report any periods of reference product exclusivity for the selected drug to the extent the determination of exclusivity is listed in the Purple Book.

Comment: A few commenters raised concerns that CMS' definitions in the Market Data Revenue and Sales Volume Data section were too broad and burdensome given the timeframe to collect data from all Secondary Manufacturers. Some commenters opposed CMS' intent to collect certain metrics such as "U.S. commercial average net unit price" and "manufacturer average net unit price to Part D plan sponsors." A few commenters requested CMS withdraw or clarify these metrics. Some commenters also were concerned with CMS requesting data on patient assistance, noting that patient assistance is not a form of price concession or remuneration. One commenter requested CMS remove all reporting of patient assistance or, minimally, clarify that patient assistance programs are defined as charitable free drug programs. One commenter noted the definitions included vague timeframes, which could lead to data discrepancies, and recommended CMS consider including firm dates in definitions. For example, the commenter suggested clarifying "quarterly total U.S. unit volume" and providing a specific quarter on which to report, including which specific quarter in the past five years. One commenter stated that the information collected pursuant to the definitions are considered confidential and proprietary information.

Response: CMS appreciates commenters' concerns. The statute requires CMS to broadly consider market data and revenue and sales data. As noted in guidance, CMS considers these

data to include WAC, Medicaid best price, AMP, FSS price, Big Four price, and U.S. commercial average net unit price, among other data. Data related to these definitions will be considered, in part, as the basis for offers and counteroffers. CMS clarified in Appendix C that patient assistance programs include manufacturer-run patient assistance programs that provide financial assistance such as coupons or copayment assistance or free drug products. In response to comments, CMS removed the metrics "manufacturer average net unit price to Part D plan sponsors" and "quarterly total U.S. unit volume." CMS removed "manufacturer average net unit price to Part D plan sponsors" because CMS does not plan to consider this information for the purposes of developing the initial offer. CMS removed "quarterly total U.S. volume" because CMS collects this information in other questions in the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW). CMS refers interested parties to the revised version of the Negotiation Data Elements ICR that is open for a 30-day public comment period through July 31, 2023. With respect to the comment about confidential and proprietary information, proprietary information, including trade secrets and confidential commercial or financial information, CMS will protect the confidentiality of any proprietary information from Primary Manufacturers or Secondary Manufacturers (described in section 40.2.1) as required under section 1193(c) of the Act and other applicable law.

Timeline for Medicare Drug Price Negotiation Program Initial Price Applicability Year 2026

Date	Milestone
June 30, 2023	Revised Negotiation Program guidance is published by CMS.
July 3, 2023	Latest date to submit Small Biotech Exception request to CMS for initial price applicability year 2026.
September 1, 2023*	CMS publishes list of up to 10 selected drugs for initial price applicability year 2026 of the Negotiation Program.
October 1, 2023*	Latest date for manufacturers of selected drugs to enter into a Medicare Drug Price Negotiation Program Agreement with CMS. Manufacturers of selected drugs without an Agreement in place are referred to IRS.
October 2, 2023*	Manufacturers' section 1194(e)(1) data submissions due to CMS. All voluntary submissions of section 1194(e)(2) data are also due on this date.
Fall 2023	CMS meets with the manufacturer of each selected drug to review data submissions, subject to manufacturer's interest in such meeting.
Fall 2023	CMS holds listening sessions with patients, consumer groups, and other interested parties to obtain input on selected drugs.
February 1, 2024*	Latest date for CMS initial offers to manufacturers for selected drugs, including concise justification of the initial offer.
March 2, 2024*	Latest date for counteroffers from manufacturers, if applicable, assuming initial offer sent to manufacturer by CMS on February 1, 2024.
April 1, 2024	Latest date for CMS to act on manufacturer counteroffer, assuming counteroffer is received by CMS on March 2, 2024. CMS may accept or decline such counteroffer.
April 1, 2024	Latest date for first CMS-manufacturer negotiation meeting to be scheduled if CMS declines the counteroffer, assuming initial offer was sent by CMS on February 1, 2024.

~April 1, 2024 through June 28, 2024	Up to three possible negotiation meetings between the manufacturer and CMS to negotiate MFP for the selected drug. Meetings can begin in late March or April depending on when CMS declines the counteroffer, if applicable, and scheduling.
July 15, 2024	Latest date for final CMS MFP offers to manufacturers if MFP not agreed to during negotiations.
July 31, 2024	Manufacturer response due to CMS regarding final CMS MFP offer.
August 1, 2024*	End of negotiation period for initial price applicability year 2026. Manufacturers of selected drugs without an MFP in place are referred to IRS.
September 1, 2024*	MFPs published for up to 10 selected drugs for 2026 for which MFP agreement has been reached with the manufacturer. CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, and the MFP file (which would be updated annually to show the inflation-adjusted MFP for a selected drug).
March 1, 2025*	CMS publishes explanation of MFP for each selected drug for which MFP agreement has been reached with the manufacturer. CMS will also release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable.
January 1, 2026*	MFPs for the selected drugs for which MFP agreement has been reached with the manufacturer go into effect.

*Denotes statutory dates

D. Revised Guidance on Medicare Prescription Drug Negotiation Program

10. Introduction

The purpose of this revised guidance is to provide interested parties with information regarding CMS' implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA) (P.L. 117-169), signed into law on August 16, 2022, which establish the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") to negotiate maximum fair prices (MFPs)[27] for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter "the Act") as added by sections 11001 and 11002 of the IRA.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary of the Department of Health and Human Services (hereafter "the Secretary") to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, the Centers for Medicare & Medicaid Services (CMS) is issuing this revised guidance for implementation of the Negotiation Program for initial price applicability year 2026.

[27] In accordance with section 1191(c)(3) of the Social Security Act, maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

This revised guidance is not subject to the notice-and-comment requirements of the Administrative Procedure Act ("APA") or the Medicare statute, due to the requirement in sections 11001(c) and 11002(c) of the IRA to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. The terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. The statutory directive in sections 11001(c) and 11002(c) thus specifies that CMS shall follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under the APA or the Medicare statute. Congress underscored this directive by placing the Negotiation Program in the newly-enacted Part E of Title XI of the Social Security Act.

Moreover, as explained in the initial memorandum, to the extent that this revised guidance establishes or changes any substantive legal standard, CMS found that notice and public procedure on this revised guidance would be impracticable, unnecessary, and contrary to the public interest in light of the statutory requirement to implement the Negotiation Program for 2026 by program instruction and in light of the complexity of the preparation that must be undertaken in advance of the publication by September 1, 2023 of the selected drug list for initial price applicability year 2026. In particular, manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture might be included on the selected drug list for initial price applicability year 2026. For example, manufacturers may need to engage in internal discussions regarding whether the manufacturer would choose to participate in the Negotiation Program if its drug is included among the selected drug list published on September 1, 2023, review the template Medicare Drug Price Negotiation Program Agreement and guidance to understand Negotiation Program requirements for participating manufacturers in advance of the statutory deadline for entering agreements of October 1, 2023, and gather information for potential submission to CMS by the statutory deadline of October 2, 2023. In addition, for the reasons explained below, the deadline for a biosimilar manufacturer to submit a delay request under section 1192(f) was May 22, 2023. CMS could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far in advance of these statutory deadlines to allow them adequate time to complete their preparations for participation in the Negotiation Program. Thus, CMS concluded that there was good cause to issue certain specified parts of the initial memorandum as final (i.e., section 30) without public comment and without a delayed effective date. Although CMS has endeavored to solicit public comment and to respond to comments to the extent that it would be feasible to do so consistent with the statutory deadlines for implementation of the Negotiation Program, CMS also concludes that there is good cause to issue this revised guidance as final without the 60-day period for public comment under the Medicare statute, and without a delayed effective date, in order to meet the statutory deadlines of the Negotiation Program and consistent with the authority provided to CMS in sections 11001(c) and 11002(c) of the IRA. *See* 5 U.S.C. § 553(b)(B) & (d)(3); *see also* section 1871(b)(2)(C) of the Act.

In this revised guidance, CMS has made clarifications and changes to the policies described in the initial memorandum in response to comments and based on CMS' further consideration of the relevant issues, including policies on which CMS did not expressly solicit comment.

This revised guidance describes how CMS will implement the Negotiation Program for initial price applicability year 2026 (January 1, 2026 to December 31, 2026), and specifies the requirements that will be applicable to manufacturers of drugs that are selected for negotiation and the procedures that may be applicable to drug manufacturers, Medicare Part D plans (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) Plans), pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D.

If any provision in this revised guidance is held to be invalid or unenforceable, it shall be severable from the remainder of this revised guidance, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances.

The table of contents for this revised guidance is as follows:

- Section 10 – Introduction
- Section 20 – Overview
- Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2026
  - 30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2026
    - 30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs
    - 30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs
    - 30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs
  - 30.2 Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2026
    - 30.2.1 Exception for Small Biotech Drugs
  - 30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026
    - 30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry
      - 30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026
      - 30.3.1.2 High Likelihood
      - 30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026
      - 30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026
  - 30.4 Publication of the Selected Drugs List
- Section 40 – Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026
  - 40.1 Entrance into an Agreement with CMS and Alternatives
  - 40.2 Submission of Manufacturer Data to Inform Negotiation
    - 40.2.1 Confidentiality of Proprietary Information
    - 40.2.2 Data and Information Use Provisions and Limitations
    - 40.2.3 Opportunity for Corrective Action Following Information Submission

- 40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years
- 40.4 Providing Access to the MFP
  - 40.4.1 Nonduplication with 340B Ceiling Price
- 40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program
- 40.6 Termination of the Agreement
- 40.7 Other Provisions in the Agreement

- Section 50 – Negotiation Factors
  - 50.1 Manufacturer-Specific Data
    - 50.1.1 Non-FAMP Data
  - 50.2 Evidence About Therapeutic Alternatives for the Selected Drug
- Section 60 – Negotiation Process
  - 60.1 Establishment of a Single MFP for Negotiation Purposes
  - 60.2 Limitations on Offer Amount
    - 60.2.1 Determination of the Ceiling for the MFP
    - 60.2.2 Sum of the Plan-Specific Enrollment Weighted Amounts
    - 60.2.3 Average Non-Federal Average Manufacturer Price
    - 60.2.4 Selection and Application of the Ceiling for the MFP
  - 60.3 Methodology for Developing an Initial Offer
    - 60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication
    - 60.3.2 Developing a Starting Point for the Initial Offer
    - 60.3.3 Adjusting the Starting Point Based on Clinical Benefit
      - 60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)
      - 60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives
      - 60.3.3.3 Preliminary Price
    - 60.3.4 Adjusting the Preliminary Price Based on Consideration of Manufacturer-Specific Data
  - 60.4 Negotiation Process
    - 60.4.1 Provision of an Initial Offer and Justification
    - 60.4.2 Required Components of a Counteroffer
    - 60.4.3 Negotiation Process After Manufacturer Counteroffer
    - 60.4.4 Determination that Negotiations Have Finished
  - 60.5 Application of the MFP Across Dosage Forms and Strengths
    - 60.5.1 Application of the MFP to New NDAs / BLAs or NDCs
  - 60.6 Publication of the MFP
    - 60.6.1 Explanation for the MFP
  - 60.7 Exclusion from the Negotiation Process Based on Generic or Biosimilar Availability
  - 60.8 Establishment of MFPs After the Negotiation Deadline
- Section 70 – Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect
- Section 80 – MFP-Eligible Individuals
- Section 90 – Manufacturer Compliance and Oversight

  - 90.1 Monitoring of Manufacturer Compliance
  - 90.2 Monitoring of Access to the MFP
  - 90.3 26 U.S.C. Section 5000D Excise Tax on Sale of Designated Drugs
  - 90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product
- Section 100 – Civil Monetary Penalties
  - 100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP
  - 100.2 Violations of the Agreement
  - 100.3 Provision of False Information Related to the Small Biotech Exception and the Biosimilar Delay Rule
  - 100.4 Notice and Appeal Procedures
- Section 110 – Part D Formulary Inclusion of Selected Drugs
- Section 120 – Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs
- Appendix A – Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026
- Appendix B – Template for the Initial Delay Request Form
- Appendix C – Definitions for Purposes of Collecting Manufacturer-Specific Data

20. Overview

In accordance with sections 11001 and 11002 of the IRA, which created Part E under Title XI of the Act (sections 1191 through 1198), the Secretary is required to establish the Negotiation Program to negotiate MFPs for certain high expenditure, single source Medicare drugs. With respect to each initial price applicability year, CMS shall (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate and, if applicable, renegotiate MFPs for such selected drugs, in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) impose civil monetary penalties (CMPs) in accordance with section 1197 of the Act. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

As noted above, in order to facilitate the timely implementation of the Negotiation Program, CMS issued section 30 of the initial memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception Information Collection Request (ICR),[28] as discussed in section 30.2.1 of this revised guidance). To allow for public input, CMS voluntarily solicited comments on all other sections of the initial memorandum except for section 90.3 (which states that the Treasury Department will issue guidance relating to the excise tax in the coming weeks), and specifically on certain topics in the initial memorandum, including:

- Terms and conditions contained in the manufacturer agreement, including the manufacturer's and CMS' responsibilities (included in section 40 of this revised guidance);

[28] This ICR was approved on May 26, 2023. Small Biotech Exception (CMS-10844; OMB Control No. 1938-1443).

- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments (included in section 60 of this revised guidance);
- Process for the offer and counteroffer exchange between CMS and manufacturers (included in section 60 of this revised guidance);
- Content of an explanation for the MFP (included in section 60 of this revised guidance);
- Method for applying the MFP across different dosage forms and strengths of a selected drug (included in section 60 of this revised guidance);
- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198 (included in section 40.5 of this revised guidance); and
- Processes for compliance monitoring and imposition of CMPs for violations (included in sections 90 and 100 of this revised guidance).

In this revised guidance, CMS has made clarifications and changes in response to comments and based on CMS' further consideration of the relevant issues, including policies on which CMS did not expressly solicit comment.

30. Identification of Selected Drugs for Initial Price Applicability Year 2026

In order to facilitate the timely implementation of the Negotiation Program in accordance with statutory deadlines, CMS issued section 30 of the initial memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception ICR, as described in section 30.2.1 of this revised guidance). While CMS did not solicit comment in response to section 30, CMS did receive many thoughtful comments, and based on these comments and further consideration of the relevant issues, CMS identified certain policies where revisions to clarify the policy described in the initial memorandum would facilitate the implementation of the Negotiation Program for initial price applicability year 2026. CMS has noted in section 30, and in the summary of key changes and clarifications, where clarifying revisions were made.

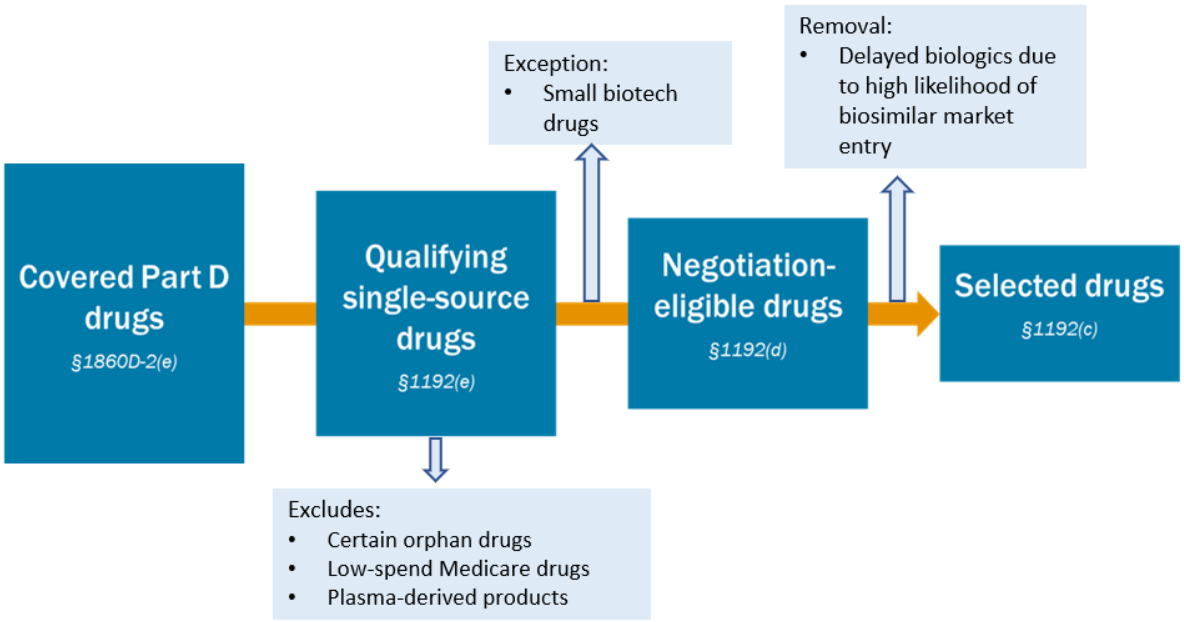
Section 1192 of the Act establishes the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs for an initial price applicability year. First, CMS will identify qualifying single source drugs in accordance with section 1192(e) of the Act, as described in section 30.1 of this revised guidance. CMS will exclude certain drugs in accordance with section 1192(e)(3) of the Act. Next, in accordance with section 1192(d) of the Act, using Total Expenditures[29] under Part D of Title XVIII for these qualifying single source drugs calculated using Part D prescription drug event (PDE) data for dates of service between June 1, 2022, and May 31, 2023, and other information described below, CMS will identify negotiation-eligible drugs for initial price applicability year

[29] For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3)). The term "gross covered prescription drug costs" is also defined in the Part D regulations at 42 C.F.R. § 423.308. In the initial memorandum, CMS indicated that it had proposed to update this regulatory definition of gross covered prescription drug costs to eliminate any potential ambiguity in the regulation text and help to ensure there is a consistent understanding of the term for purposes of both the Part D program and the IRA. Since the initial memorandum was issued, CMS has issued a final rule adopting the proposed revisions to 42 C.F.R. § 423.308. (See Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Final Rule (0938-AU96), 88 Fed. Reg. 22,120, 22,259 (Apr. 12, 2023)).

2026 as described in section 30.2 of this revised guidance (in this step, CMS will also exclude certain drugs in accordance with section 1192(d)(2) and (3) of the Act).

In accordance with section 1192(d)(1) of the Act, CMS will rank negotiation-eligible drugs for initial price applicability year 2026 according to the Total Expenditures for such drugs under Part D of Title XVIII for the 12-month period described above (described in section 30.3 of this revised guidance). In accordance with section 1192(a) of the Act and subject to the Special Rule to delay the selection and negotiation of biologics for biosimilar market entry described in section 1192(f) of the Act, CMS will select the 10 negotiation-eligible drugs with the highest Total Expenditures under Part D of Title XVIII for negotiation for initial price applicability year 2026 (described in section 30.3 of this revised guidance) and publish a list of those ten selected drugs not later than September 1, 2023 (described in section 30.4 of this revised guidance). Figure 1 provides a visual depiction of this process, and detailed guidance pertaining to this process for initial price applicability year 2026 is included below.

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2026



30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2026

For initial price applicability year 2026, in accordance with section 1192(e)(1) of the Act, CMS will define a qualifying single source drug as a covered Part D drug (as defined in section 1860D-2(e) of the Act) that meets the following criteria:

- For drug products, a qualifying single source drug is a drug (1) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the

date of such approval; and (3) that is not the listed drug for any drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act.

- For biological products, a qualifying single source drug is a biological product (1) that is licensed under section 351(a) of the Public Health Service Act (PHS Act) and marketed pursuant to such licensure; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 11 years have elapsed since the date of such licensure; and (3) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act.

Section 1192(d)(3)(B) of the Act states that CMS shall use data that are aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or package type of the drug for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug under section 1192(d)(1) of the Act and applying the exception for small biotech drugs under section 1192(d)(2) of the Act. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures "to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug."

Identifying potential qualifying single source drugs:
In accordance with the statutory language cited above, for purposes of the Negotiation Program, CMS will identify a potential qualifying single source drug[30] using:

- For drug products, all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA)[31], inclusive of products that are marketed pursuant to different NDAs. The potential qualifying single source drug will also include all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such NDA(s), (2) authorized generic drugs that are marketed pursuant to such NDA(s), and (3) multi-market approval (MMA) products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s);
- For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA),[32] inclusive of products that are marketed pursuant to different BLAs. The potential qualifying single source drug will also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such BLA(s), (2) authorized biologic products that are marketed pursuant to such BLA(s), and (3) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such BLA(s).

[30] Throughout this revised guidance, a qualifying single source drug means the specific constituent dosage forms and strengths (at the NDC-9 or NDC-11 level) that are identified as aggregated under the NDA(s) / BLA(s) for the active moiety / active ingredient as outlined in section 30.1 of this revised guidance.
[31] As described in section 505(c) of the FD&C Act.
[32] As described in section 351(a) of the PHS Act.

As an example, entity A holds three NDAs for drug products with the same active moiety approved in NDA-1, NDA-2, and NDA-3. Entity A manufactures and markets three different strengths as an immediate release tablet pursuant to NDA-1, three different strengths as an extended-release tablet pursuant to NDA-2, and three different strengths as a subcutaneous injectable pursuant to NDA-3. Additionally, under an agreement with entity A, entity B repackages three strengths of the immediate release tablets manufactured by entity A and markets them pursuant to NDA-1. In this scenario, all 12 of these drug products, including the repackaged products, will be aggregated as a single potential qualifying single source drug for purposes of identifying negotiation-eligible drugs.

This approach to identifying a potential qualifying single source drug aligns with the requirement in section 1192(d)(3)(B) of the Act to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. Consistent with this statutory instruction, this approach is also appropriate because CMS is aware that new dosage forms or different routes of administration of the same active moiety / active ingredient have been submitted by the same NDA / BLA holder and approved under different NDAs or BLAs.

Section 1192(e)(2)(A) of the Act states that an authorized generic drug and the qualifying single source drug that is the listed drug or reference product of that authorized generic drug shall be treated as the same qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act as (1) in the case of a drug product, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act), and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act[33] and is marketed, sold, or distributed, directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark.

If a drug is a fixed combination drug[34] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs. Therefore, all formulations of this distinct combination offered by the same NDA / BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties / active ingredients that is offered by the same NDA / BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. For example, a long-acting corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA / BLA holder that contains the same corticosteroid combined with a long-acting beta agonist. In this example, the long-acting corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

[33] CMS is interpreting the reference to "licensed under section 351(a) of such Act" to mean licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.
[34] For purposes of the Negotiation Program, the term "fixed combination drug" has the meaning specified in 21 C.F.R. § 300.50.

Applying statutory criteria for qualifying single source drugs:
In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, at least 7 years (for drug products) or 11 years (for biological products) must have elapsed between the U.S. Food and Drug Administration (FDA) date of approval or licensure, as applicable, and the selected drug publication date. To determine the date of approval or licensure for a potential qualifying single source drug with more than one FDA application number, CMS will use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA / BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients. The selected drug publication date for initial price applicability year 2026 is September 1, 2023, as specified in section 1191(d)(1) of the Act. As such, for initial price applicability year 2026, the initial approval for a drug product to be considered a qualifying single source drug must have been on or before September 1, 2016, and the date of initial licensure for a biological product to be considered a qualifying single source drug must have been on or before September 1, 2012.

For example, if 12 years had elapsed between the original approval for NDA-1 cited in the previous example above and September 1, 2023, then the potential qualifying single source drug defined above would meet this statutory criterion for qualifying single source drugs (even if less than seven years had elapsed between the approval dates for NDA-2 or NDA-3 and September 1, 2023), consistent with the statutory directives in section 1192(d)(3)(B) of the Act to aggregate data across dosage forms and strengths of the drug, including new formulations of the drug.

In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, a product cannot be the listed drug for any drug approved and marketed under an ANDA under section 505(j) of the FD&C Act, and a biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act. CMS will use FDA reference sources, including the Orange Book[35] and Purple Book,[36] to determine whether a generic drug or biosimilar biological product has been approved or licensed for any of the strengths or dosage forms of the potential qualifying single source drugs for initial price applicability year 2026.

In accordance with section 1192(c) and (e) of the Act for the purpose of identifying qualifying single source drugs for initial price applicability year 2026, CMS is clarifying in this revised guidance that it will review PDE data for the 12-month period beginning August 16, 2022 and ending August 15, 2023, using PDE data available on August 16, 2023, as well as Average Manufacturer Price (AMP)[37] data for the 12-month period beginning August 1, 2022 and ending July 31, 2023, using the AMP data available on August 16, 2023, for a given generic drug or biosimilar biological product for which a potential qualifying single source drug is the listed drug or reference product. The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry, but these sources of data over the specified intervals

[35] See: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.
[36] See: https://purplebooksearch.fda.gov/.
[37] Average Manufacturer Price means, with respect to a covered outpatient drug of a manufacturer for a rebate period (calendar quarter), the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and, (ii) retail community pharmacies that purchase drugs directly from the manufacturer, subject to certain exclusions. See section 1927(k)(1) of the Act.

will be informative for that determination. CMS will consider a generic drug or biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product (see section 70 of this revised guidance for additional details). CMS has chosen these time periods to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published by September 1, 2023 in accordance with section 1192(a) of the Act.

If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar biological products that CMS determines are approved and marketed based on the process described in this revised guidance, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026. If CMS determines that the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026 because a manufacturer of such generic drug or biosimilar biological product has engaged in bona fide marketing of the generic drug or biosimilar biological product, CMS will monitor to ensure continued bona fide marketing of the generic drug or biosimilar biological product based on the approach described in section 90.4 of this revised guidance.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(A) of the Act, CMS will exclude certain orphan drugs when identifying qualifying single source drugs ("the Orphan Drug Exclusion"). Specifically, CMS will exclude a drug or biological product that is designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and for which the only approved indication (or indications) is for such disease or condition. To be considered for the Orphan Drug Exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition. CMS is clarifying in this revised guidance that a drug that has orphan designations for more than one rare disease or condition will not qualify for the Orphan Drug Exclusion, even if the drug has not been approved for any indications for the additional rare disease(s) or condition(s). CMS further clarifies that it will consider only active designations and active approvals when evaluating a drug for the Orphan Drug Exclusion; that is, CMS will not consider withdrawn orphan designations or withdrawn approvals as disqualifying a drug from the Orphan Drug Exclusion.

In order to qualify for the Orphan Drug Exclusion, all dosage forms and strengths of the qualifying single source drug described in section 30.1 of this revised guidance must meet the criteria for exclusion. CMS will use the FDA Orphan Drug Product designation database[38] and approvals on the FDA website[39] to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the Orphan Drug Exclusion. CMS will also consult with FDA as needed, including to determine whether a drug is designated for, or approved for indications for, one or more rare disease(s) or condition(s). In this revised guidance, CMS is clarifying that, in the event that a drug or biological product loses Orphan Drug Exclusion status,

[38] See: https://www.accessdata.fda.gov/scripts/opdlisting/oopd/.
[39] See: https://www.accessdata.fda.gov/scripts/cder/daf/.

pursuant to sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act, CMS will use the date of the earliest approval or licensure of the drug or biological product (as described above in section 30.1) to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Act.

As noted in the initial memorandum, CMS is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development, and CMS appreciates continued input from interested parties on this topic. Additional information about how CMS will consider the impact of a selected drug (and its therapeutic alternative(s)) on specific populations as well as the extent to which the selected drug (and its therapeutic alternative(s)) meets an unmet medical need in CMS' development of an initial offer is in section 60.3.3 of this revised guidance.

30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(B) of the Act, CMS will also exclude low-spend Medicare drugs or biological products with less than $200,000,000 in combined expenditures under Medicare Parts B and D when identifying qualifying single source drugs ("the Low-Spend Medicare Drug Exclusion"). For initial price applicability year 2026, CMS will identify low-spend Medicare drugs as follows:

- CMS will identify PDE data combined with Part B claims data for each potential qualifying single source drug for dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. To allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been submitted no later than 30 days[40] after May 31, 2023, i.e., by June 30, 2023. To allow a reasonable amount of time for providers and suppliers to submit Part B claims, CMS will use Part B claims data for the dates of service described above that have been submitted no later than 30 days after May 31, 2023, i.e., by June 30, 2023.
- For each potential qualifying single source drug as described in section 30.1 of this revised guidance, CMS will use the PDE data to calculate the Total Expenditures under Part D and CMS will use the Part B claims data to calculate the total allowed charges under Part B, inclusive of beneficiary cost sharing, for purposes of determining Total Expenditures under Part B. CMS is clarifying in this revised guidance that expenditures for a drug or biological product that are bundled or packaged into the payment for another service will be excluded from the calculation of total allowed charges under Part B.
- CMS will exclude from the final list of qualifying single source drugs for initial price applicability year 2026 any drugs for which the sum of Total Expenditures under Part D and Part B is less than $200 million.

[40] For purposes of this revised guidance, CMS defines all days as calendar days unless otherwise specified in statute, guidance, or regulation.

30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(C) of the Act, CMS will exclude plasma-derived products when identifying qualifying single source drugs as described in section 30.1 of this revised guidance ("the Plasma-Derived Product Exclusion"). For purposes of this exclusion, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling. CMS will refer to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[41] and will refer to the FDA Online Label Repository[42] to verify if the product is derived from human whole blood or plasma. CMS will also consult with FDA as needed.

30.2 Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2026

In accordance with sections 1192(a) and 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2026 is a qualifying single source drug that is among the 50 qualifying single source drugs with the highest Total Expenditures under Part D. CMS will identify the negotiation-eligible drugs for initial price applicability year 2026 as follows:

- CMS will identify all qualifying single source drugs for initial price applicability year 2026 using the process described in section 30.1 of this revised guidance. CMS will exclude any drugs that qualify for the exclusions listed in sections 30.1.1 – 30.1.3 of this revised guidance.
- CMS will identify PDE data for each NDC-11 of a qualifying single source drug for dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been accepted no later than 30 days after May 31, 2023, i.e., by June 30, 2023.
- CMS will use this PDE data to calculate the Total Expenditures under Part D for each qualifying single source drug during the 12-month applicable period.
- CMS will (1) remove drugs that are subject to the exception for small biotech drugs, described in section 30.2.1 of this revised guidance; (2) rank the remaining qualifying single source drugs by Total Expenditures under Part D during the applicable 12-month period; and (3) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part D during the applicable 12-month period.
- These 50 drugs will be considered negotiation-eligible drugs for initial price applicability year 2026.

When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part D, and such Total Expenditures are the 50th highest among qualifying single source drugs, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number with its active moiety(ies) / active ingredient(s), until CMS has identified 50 negotiation-eligible drugs. CMS believes that this approach would not be likely to alter which drugs are selected drugs because a maximum of 10 drugs will be selected for initial price applicability year 2026 (see section 30.3 of this revised guidance for details).

[41] See: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[42] See: https://labels.fda.gov/.

30.2.1 Exception for Small Biotech Drugs

In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs ("the Small Biotech Exception"). The statute requires that CMS consider, for Part D drugs, Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures for the qualifying single source drug under Part D during 2021, and Total Expenditures under Part D for all covered Part D drugs for which the manufacturer that had a Coverage Gap Discount Program (CGDP) agreement in effect under section 1860D-14A of the Act for the qualifying single source drug during 2021 also had a CGDP agreement in effect during 2021.[43] To identify and exclude such small biotech drugs, CMS will consider whether, for dates of services in calendar year 2021, the Total Expenditures under Part D for the qualifying single source drug (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the qualifying single source drug had a CGDP agreement in effect during 2021.

For the purposes of the Small Biotech Exception for initial price applicability year 2026, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all entities that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 with the entity that had the CGDP agreement for the qualifying single source drug on that date. However, CMS does not have information about which entities were treated as a single employer under the applicable IRC provisions. Therefore, a manufacturer that seeks the Small Biotech Exception for its qualifying single source drug ("Submitting Manufacturer") must submit information to CMS about the company and its products in order for the drug to be considered for the exception. To the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the NDA(s) / BLA(s) for the qualifying single source drug may be the Submitting Manufacturer. CMS made this decision to ensure that only the entity with which CMS would negotiate in the event that the qualifying single source drug is selected for negotiation, as described in section 40 of this revised guidance, is able to seek the Small Biotech Exception.

On January 24, 2023, CMS released the Small Biotech Exception ICR (CMS-10844 / OMB 0938-1443) to detail the specific data that CMS is requesting for purposes of implementing this exception. The comment period in response to the 60-day notice closed on March 27, 2023. CMS released a revised version of the Small Biotech Exception ICR on April 24, 2023, and the comment period in response to the 30-day Federal Register notice closed on May 24, 2023. CMS published the final, approved version of the Small Biotech Exception ICR on May 26, 2023.[44]

[43] For the purposes of this determination, a manufacturer that participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's CGDP agreement would be considered to have had an agreement in effect during 2021.

[44] To view the Small Biotech ICR Form, a summary of changes made to the Small Biotech ICR in response to comments received during the 60-day and 30-day notice periods, as well as comments received on the Small Biotech ICR and CMS' responses to those comments, see https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016.

The Small Biotech Exception ICR addresses the collection of information for initial price applicability year 2026 only. For initial price applicability year 2026, Sections 1191(a) and 1192(d) of the Act require CMS to evaluate whether a qualifying single source drug qualifies as a negotiation-eligible drug under 1192(d) based on Total Expenditures under Part D only, including with respect to the Small Biotech Exception. As a result, this ICR addresses the collection of information relevant to Total Expenditures only under Part D. Additionally, this ICR does not address the collection of information relevant to the statutory limitation found in section 1192(d)(2)(B)(ii) of the Act (which precludes the application of the Small Biotech Exception to a qualifying single source drug if the manufacturer of that drug is acquired after 2021 by a manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) because the earliest effective date specified in that limitation (January 1, 2025) has no impact until initial price applicability year 2027 (the first initial price applicability year with a selected drug publication date after January 1, 2025).

As CMS announced on May 26, 2023, after approval of the ICR, to receive consideration for the Small Biotech Exception for initial price applicability year 2026, the Submitting Manufacturer must submit the Small Biotech Exception ICR Form using the CMS Health Plan Management System (CMS HPMS) by July 3, 2023.[45] CMS will notify the Submitting Manufacturer in September 2023 of the determination of whether the Submitting Manufacturer's qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026. CMS is clarifying in this revised guidance that information in a Small Biotech Exception ICR Form that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)).

CMS will not consider incomplete submissions. Upon receipt of a complete Small Biotech Exception ICR Form, CMS will take the following approach to identify whether a qualifying single source drug qualifies for the Small Biotech Exception:

- CMS will identify the manufacturer that had a CGDP agreement for the qualifying single source drug in effect as of December 31, 2021 ("2021 Manufacturer") based on the information submitted in the Small Biotech Exception ICR Form.
- CMS will use the information submitted in that form to identify the complete set of 11-digit National Drug Codes (NDC-11s)[46] for which any member of the 2021 Manufacturer's controlled group as of December 31, 2021 had a CGDP agreement as of December 31, 2021. "Controlled group" means all corporations or partnerships, proprietorships and other entities treated as a single employer under 26 U.S.C. § 52(a) or (b).
- Using the complete set of NDC-11s for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect on December

[45] On June 2, 2023, CMS released the Small Biotech Exception functionality in CMS HPMS, and manufacturers could begin submitting their requests on that date. To view instructions for requesting the Small Biotech Exception in CMS HPMS, see https://www.cms.gov/files/document/small-biotech-exception-guidance-6223.pdf.

[46] NDC-9 and NDC-11 numbers are identical except for two numbers in NDC-11s that indicate package size. Because of this, NDC-11 is more granular than NDC-9, and multiple NDC-11 numbers can aggregate under a single NDC-9 number.

31, 2021, CMS will identify PDE data for dates of service during the 12-month period beginning January 1, 2021 and ending December 31, 2021.

- Using the PDE data for (1) the qualifying single source drug, (2) the complete set of covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement as of December 31, 2021, and (3) all covered Part D drugs, CMS will determine whether:
    - The Total Expenditures under Part D for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and
    - The Total Expenditures under Part D for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect during 2021.

  CMS is clarifying in this revised guidance that the Total Expenditures under Part D for all covered Part D drugs will be determined using PDE data for all covered Part D drugs. The Total Expenditures under Part D for the qualifying single source drug and the Total Expenditures under Part D for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect during 2021 will only include PDE data for NDC-11s with labeler codes associated with the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group.

For initial price applicability year 2026, the term "negotiation-eligible drug" will exclude any covered Part D drugs that are qualifying single source drugs that meet these criteria to qualify for the Small Biotech Exception.

A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years. The Submitting Manufacturer must resubmit a request for the drug to be considered for the exception for initial price applicability years 2027 and 2028. The process for resubmitting a request will be addressed in future guidance.

In this revised guidance, CMS is clarifying that it will publish the number of drugs that applied for and received the Small Biotech Exception for initial price applicability year 2026 as part of publishing the selected drug list on September 1, 2023.

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026

In accordance with sections 1192(a) and 1192(b) of the Act, CMS will select 10 (or all, if such number is less than 10) negotiation-eligible drugs for initial price applicability year 2026 as follows:

- CMS will rank the 50 negotiation-eligible drugs identified in section 30.2 of this revised guidance by Total Expenditures under Part D (based on the data described in section 30.2 of this revised guidance) in descending order: the negotiation-eligible drug with the highest Total Expenditures under Part D will be listed first and the negotiation-eligible drug with the lowest Total Expenditures under Part D will be listed last.

- CMS will remove any biological products that qualify for delayed selection under section 1192(f) of the Act as described in section 30.3.1 of this revised guidance.
- CMS will select for negotiation the 10 (or all, if such number is less than 10) highest ranked negotiation-eligible drugs remaining on the ranked list for initial price applicability year 2026.
    - In the event that two or more negotiation-eligible drugs have the same Total Expenditures under Part D to the dollar and such Total Expenditures are the 10th highest among negotiation-eligible drugs, CMS will rank those negotiation-eligible drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the initial FDA application number for its active moiety(ies) / active ingredient(s), and select based on that ranking until there are 10 selected drugs (or until all drugs are selected if the number of negotiation-eligible drugs is less than 10).

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

In accordance with section 1192(b)(1)(C) of the Act, CMS will remove from the ranked list of 50 negotiation-eligible drugs described in section 30.3 of this revised guidance any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. This section 30.3.1 describes the implementation of section 1192(f) of the Act (the "Biosimilar Delay").

Under section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by FDA. CMS believes that this approach is appropriate because (1) it clearly identifies one manufacturer that may submit a Biosimilar Delay request for a given Biosimilar, avoiding the possibility that CMS would receive two such requests naming the same Biosimilar for the same initial price applicability year, and (2) the status of the application for licensure for the Biosimilar is material to CMS' consideration of a Biosimilar Delay request, as described in this section 30.3.1.

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year ("Additional Delay Request") as stated in section 1192(f)(1)(B)(i)(II) of the Act.

The following subsections of this section 30.3.1 include details on the implementation of the Biosimilar Delay for initial price applicability year 2026. Topics related to future initial price applicability years (including Additional Delay Requests) will be covered in future guidance.

30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026

The statute specifies that the following requirements must be met in order for CMS to grant an Initial Delay Request:

1. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be, absent the Biosimilar Delay, a selected drug for the initial price applicability year.
    - Biosimilar Manufacturers that think that a Reference Drug for their Biosimilar may be a selected drug for initial price applicability year 2026 may submit an Initial Delay Request, and CMS will disregard that application if the Reference Drug would not, in fact, be a selected drug for initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug.
2. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests submitted with respect to initial price applicability year 2026, this means that the Reference Drug must have received its initial BLA licensure between January 1, 2010, and January 1, 2014.
    - Section 1194(c)(4)(B)(ii) of the Act specifies that selected drugs for which a manufacturer had an agreement under the Negotiation Program for an initial price applicability year prior to 2030 are excluded from the definition of extended-monopoly drugs. Importantly, however, an Initial Delay Request must be submitted by a Biosimilar Manufacturer before the selected drug publication date for an initial price applicability year and before the Primary Manufacturer (as defined in section 40 of this revised guidance) of the Reference Drug ("Reference Manufacturer") would have entered into an agreement under the Negotiation Program. Therefore, CMS believes the exception to the definition of "extended-monopoly drug" in section 1194(c)(4)(B)(ii) of the Act will not apply at the time that a delay would be requested for initial price applicability years 2026 through 2029. Accordingly, CMS believes that the Biosimilar Delay under section 1192(f) of the Act is applicable beginning with initial price applicability year 2026. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2026, provided that the Reference Drug named in the request will have been licensed for between 12 and 16 years prior to the start of the initial price applicability year on January 1, 2026.
3. In accordance with section 1192(f)(1)(A) of the Act, the Reference Drug must include the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by the FDA or accepted for review, as described below in section 30.3.1.2 of this revised guidance.
    - Please note that in order for CMS to grant an Initial Delay Request, the licensure application for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval.

4. In accordance with section 1192(f)(2)(D)(iii) of the Act, an Initial Delay Request cannot be granted if more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
    - For Initial Delay Requests submitted with respect to initial price applicability year 2026, this requirement means that if the Biosimilar has already received approval by the FDA for its application for licensure under section 351(k) of the PHS Act, the date of such licensure must be on or after September 1, 2022 for a delay to be granted. If the Biosimilar is already licensed and marketed by September 1, 2023, the selected drug publication date for initial price applicability year 2026, the Reference Drug would by definition no longer be a qualifying single source drug and therefore would fail requirement #1 on this list. If the Biosimilar was licensed prior to September 1, 2022 and is not marketed before September 1, 2023, more than one year would have elapsed since the licensure of the Biosimilar without marketing of the Biosimilar having commenced.
5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC of 1986, or in a partnership, shall be treated as one manufacturer, as stated in section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, "partnership" is defined at section 1192(f)(1)(C)(ii) of the Act as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer.
6. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that either:
    - requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
    - directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time. For Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after September 1, 2023 as violating this requirement.
7. In accordance with section 1192(f)(1)(A) of the Act and as described in detail in section 30.3.1.2 of this revised guidance, CMS must determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year.

30.3.1.2 High Likelihood

In accordance with section 1192(f)(1)(A) of the Act, CMS will review Initial Delay Requests to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year. Accordingly, for Initial Delay Requests submitted with respect to initial price

applicability year 2026, CMS must find a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, in order to grant the request. If CMS does not find that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described below, CMS will deny the Initial Delay Request.

In accordance with section 1192(f)(3) of the Act, Initial Delay Requests must demonstrate both of the following in order meet the high likelihood threshold:

1. An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA.[47]
    - For Initial Delay Requests submitted with respect to initial price applicability year 2026, the Biosimilar's application for licensure must be approved or accepted for review by the FDA no later than August 15, 2023, in order to permit CMS time to review the information and finalize the selected drug list prior to the selected drug publication date of September 1, 2023.
    - Please note that if the Biosimilar's application for licensure has not been accepted for review by August 15, 2023, including in the case where the Biosimilar Manufacturer has submitted an application for licensure that has not been accepted for review by the FDA or for which a filing determination is pending, CMS will deny the Initial Delay Request for initial price applicability year 2026.
2. Clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025 (the date that is two years after the selected drug publication date for the initial price applicability year), based on the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS.

For Initial Delay Requests submitted for initial price applicability year 2026, to demonstrate clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025, CMS requires that the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS by the Biosimilar Manufacturer as part of its Initial Delay Request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date, and so CMS believes that evidence showing that a Biosimilar meets these two requirements is sufficient to establish clear and convincing evidence that the Biosimilar will be marketed.

First, the Initial Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025. CMS is clarifying in this revised guidance that, in its evaluation of whether this requirement is met, CMS will only consider patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. Specifically, CMS will consider this requirement met if (1) there are no unexpired patents relating to the reference product included in the Reference

[47] CMS is clarifying in this revised guidance that it will consider an application for licensure under section 351(k) of the PHS Act that has been accepted for review and that received a Complete Response letter to meet the section 1192(f)(3)(A) requirement that an application for licensure under section 351(k) for the biosimilar biological product has been accepted for review by FDA.

Drug that are applicable to the Biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer.[48] CMS will deny all Initial Delay Requests for Biosimilars that do not meet this requirement with respect to at least one reference product included in the Reference Drug. However, active litigation related to another reference product included in the Reference Drug that is not applicable to the Biosimilar will not be disqualifying.

Second, the Initial Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before September 1, 2025. To assess this requirement, CMS will consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before September 1, 2025, and (2) a manufacturing schedule that is consistent with the public-facing statements and, as clarified in this revised guidance, demonstrates readiness to meet revenue expectations. CMS chose these criteria because they are indicative of operational readiness and should be available in the elements that CMS must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act.

In determining whether an Initial Delay Request satisfies the high likelihood threshold, CMS may use all the information described in section 30.3.1.3 of this revised guidance to determine whether an application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA. In accordance with section 1192(f)(3)(B) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025:

- All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and
- Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the two years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies.

[48] As described in section 30.3.1.1 of this revised guidance, an Initial Delay Request will not be granted if the Biosimilar Manufacturer enters into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request or directly or indirectly restricts the quantity of the Biosimilar sold in the United States on or after September 1, 2023.

In accordance with section 1198(2) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1192(f) of the Act.

30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026

A Biosimilar Manufacturer intending to submit an Initial Delay Request for initial price applicability year 2026 was required to submit a complete request by 11:59 pm PT on May 22, 2023. The process for Biosimilar Manufacturers to submit an Initial Delay Request, including the required documentation, for initial price applicability year 2026 is detailed below.

A Biosimilar Manufacturer should have submitted an Initial Delay Request for initial price applicability year 2026 only if it (1) plans for its Biosimilar to be licensed and marketed before September 1, 2025, (2) believes its request will satisfy the statutory requirements for granting an Initial Delay Request, as described in section 30.3.1.1 of this revised guidance, and (3) believes that its request demonstrates that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described in section 30.3.1.2 of this revised guidance.[49]

CMS has designed the process for Initial Delay Request submission for initial price applicability year 2026 to allow CMS time to adjudicate all requests in advance of September 1, 2023, the selected drug publication date, and to be operationally feasible. For initial price applicability year 2026, CMS accepted Initial Delay Requests submitted via email and Box[50] as described below, whereas, for future initial price applicability years, CMS plans to issue guidance on use of the CMS HPMS to receive and process these requests. Accordingly, Initial Delay Requests for initial price applicability year 2026 were able to be submitted via the following process:

1. The Biosimilar Manufacturer emailed IRARebateandNegotiation@cms.hhs.gov to indicate its intention to submit an Initial Delay Request for initial price applicability year 2026. The Biosimilar Manufacturer was encouraged to use the template, including subject line and body content, described in Appendix A of this revised guidance. Emails must have been received by 11:59 pm PT on May 10, 2023.
2. Within 5 business days of receipt, CMS responded by providing the Biosimilar Manufacturer with (1) a fillable template for the Initial Delay Request form, available in Appendix B of this revised guidance, and (2) access to a Box folder specific to the Biosimilar Manufacturer's Initial Delay Request. No parties other than the Biosimilar Manufacturer and CMS and its contractors have access to this folder.
3. The Biosimilar Manufacturer must have uploaded a complete Initial Delay Request with the following documentation to the Box folder or using an alternative submission approach approved by CMS by 11:59 pm PT on May 22, 2023. CMS deemed an Initial Delay Request to be complete if it included:

[49] For initial price applicability year 2026, an Initial Delay Request should have been submitted by a Biosimilar Manufacturer that anticipated the reference product for its Biosimilar will be included in one of the ten covered Part D Drugs that will be a selected drug for this initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug for a future initial price applicability year.

[50] See: https://www.box.com/; if a Biosimilar Manufacturer is unable to use Box, it should have included an explanation in its email in step #1 below and request an alternative submission method.

a. A complete Initial Delay Request form using the fillable template that the Biosimilar Manufacturer received from CMS. This template allowed submission of:
    i. information used to identify the Biosimilar Manufacturer, the Biosimilar, the Biosimilar's reference product, and the Reference Manufacturer;
    ii. attestations that the Initial Delay Request meets the statutory requirements listed in section 30.3.1.1 of this revised guidance; and
    iii. information on the status of licensure for the Biosimilar under section 351(k) of the PHS Act;
b. All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
c. The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
d. Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the two years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.

In accordance with section 1192(f)(1)(B)(ii) of the Act, Initial Delay Requests for initial price applicability year 2026 that were not submitted by 11:59 pm PT on May 22, 2023 or that did not include all elements will be denied. CMS is clarifying in this revised guidance that information in an Initial Delay Request that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).

30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026

Within 5 business days after the Biosimilar Manufacturer uploaded the required documentation to its Box folder or using an alternative submission approach approved by CMS, CMS sent an email confirming receipt to the email address used by the Biosimilar Manufacturer in its initial email to CMS expressing its intent to submit an Initial Delay Request. In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Initial Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request. For initial price applicability year 2026, CMS made any such follow-up request in writing to the Biosimilar Manufacturer via the same email address on or before June 20, 2023. Any such written request specified the additional information required, the format and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information, which will be no later than July 3, 2023. The one exception to these deadlines

is as follows: per section 30.3.1.2 of this revised guidance, for CMS to determine that there is a high likelihood of the Biosimilar being licensed and marketed prior to September 1, 2025, the Biosimilar's application for licensure must be accepted for review or approved by the FDA no later than August 15, 2023. CMS will permit the Biosimilar Manufacturer to update CMS on the status of the Biosimilar's application for licensure before 11:59 pm Pacific Time (PT) on August 15, 2023, in order to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published on September 1, 2023, in accordance with section 1192(a) of the Act.

Prior to September 1, 2023, the selected drug publication date for initial price applicability year 2026, CMS will review each Initial Delay Request in the following manner. First, CMS will review each Initial Delay Request to determine whether it includes all of the elements for an Initial Delay Request and was submitted by the applicable deadline in accordance with section 30.3.1.3 of this revised guidance. Second, if an Initial Delay Request includes all required elements and was timely submitted, CMS will review the Initial Delay Request to determine if it meets all of the statutory requirements described in section 30.3.1.1 of this revised guidance, with the exception of the high likelihood requirement. Third, if the Initial Delay Request meets all statutory requirements other than the high likelihood requirement, CMS will review the Initial Delay Request to determine whether it demonstrates a high likelihood that the Biosimilar will be licensed and marketed by September 1, 2025, as described in section 30.3.1.2 of this revised guidance. In considering an Initial Delay Request, CMS will cease consideration upon finding that the Initial Delay Request has failed to meet any of these requirements. For example, if CMS determines an Initial Delay Request was not submitted by the established deadline, CMS will not review that request against other statutory requirements; if CMS determines an Initial Delay Request fails to meet one or more of the statutory requirements described in section 30.3.1.1 of this revised guidance, with the exception of the high likelihood requirement, CMS will not consider whether that Initial Delay Request demonstrates a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

The list of selected drugs published for initial price applicability year 2026 will reflect the results of CMS' determinations with respect to any Initial Delay Requests that are submitted, i.e., a Reference Drug that, absent a successful Initial Delay Request, would have been selected, will not appear on the selected drug list published by September 1, 2023 if it is named in a successful Initial Delay Request.

After completing its review, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2026 in writing of CMS' determination regarding such request. This notification will occur on or after September 1, 2023, but no later than September 30, 2023, and will include a brief summary of CMS' determination, including:

- Whether the Initial Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined that the Initial Delay Request was unsuccessful, including but not limited to:
    - failure to submit all elements of the Initial Delay Request by the applicable deadline;
    - failure to meet another statutory requirement for granting a request (other than the high likelihood requirement), including in the case that the Reference Drug would

not have been a selected drug for initial price applicability year 2026 absent the Initial Delay Request; or

- failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

CMS will also notify each Reference Manufacturer named in a successful Initial Delay Request using the CMS HPMS to identify the relevant point(s) of contact. Such notification will be in writing and will identify the Reference Drug that would have been a selected drug in initial price applicability year 2026, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests will not be notified. In this revised guidance, CMS is clarifying that it will publish the number of Reference Drugs that would have been selected drugs for initial price applicability year 2026, absent successful Initial Delay Requests, as part of publishing the selected drug list on September 1, 2023.

In accordance with section 1192(f)(2)(B) of the Act, CMS must determine whether each Biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period. For successful Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will make this determination by mid-2024; CMS is still determining the appropriate date by which this determination should be made and plans to publish a specific date in future guidance. The timing, content, and format of this notification will be specified in future guidance.

The following table provides a summary of key dates related to implementation of the Biosimilar Delay for initial price applicability year 2026, as specified in this section 30.3.1:

Date	Deadline / milestone
11:59 pm PT on May 10, 2023	Deadline for Biosimilar Manufacturer to email CMS regarding intent to submit Initial Delay Request for initial price applicability year 2026
11:59 pm PT on May 22, 2023	Deadline for Biosimilar Manufacturer to submit the documentation for its Initial Delay Request as specified in section 30.3.1.3 of this revised guidance
June 20, 2023	Deadline for CMS to request follow-up information for a submitted Initial Delay Request, if applicable
July 3, 2023	Deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS, if applicable
11:59 pm PT on August 15, 2023	Deadline for Biosimilar application for licensure to be accepted for review or approved by the FDA; deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS related to the Biosimilar application for licensure
September 1, 2023	Statutory deadline for CMS to publish the selected drug list for initial price applicability year 2026. Along with the selected drug list, CMS will publish the number of drugs that would have been selected drugs, absent successful Initial Delay Requests.
September, 2023	CMS informs each Biosimilar Manufacturer that submitted an Initial Delay Request of the results of such request, in writing; for successful Initial Delay Requests, CMS also informs the Reference Manufacturer
Mid-2024[51]	For successful Initial Delay Requests, CMS determines whether the Biosimilar has been licensed and marketed during the initial delay period

Information on other policies related to section 1192(f) of the Act will be included in future guidance, including, but not limited to:

- the deadline and process for submitting an Initial Delay Request for initial price applicability year 2027;
- the deadline and process for submitting an Additional Delay Request for initial price applicability year 2027, in the event an Initial Delay Request for initial price applicability year 2026 is granted and CMS determines by mid-2024 that the Biosimilar was not licensed and marketed during the initial delay period;[52]
- the criteria for adjudicating Additional Delay Requests;
- the impact of Initial Delay Requests and Additional Delay Requests on the selected drug list for initial price applicability year 2027; and
- the application and calculation of rebates for a Reference Drug for 2026, as applicable.

30.4 Publication of the Selected Drug List

In accordance with section 1192(a) of the Act, CMS will publish the selected drug list for initial price applicability year 2026 no later than September 1, 2023. This list will include the 10 (or all, if such number is less than 10) drugs selected for negotiation for initial price applicability year 2026, including the active moiety / active ingredient for each selected drug, and the list of NDC-9s and NDC-11s for the selected drug that either had PDE utilization in the 12-month period

[51] CMS plans to publish a specific date in future guidance.
[52] CMS plans to publish a specific date in future guidance.

beginning June 1, 2022 and ending May 31, 2023 or that CMS believes are likely to have PDE utilization in the future (for example, NDC-11s associated with recently approved NDAs / BLAs).[53] CMS will post the selected drug list on the CMS IRA webpage and update this list in accordance with the process described in section 40.2 of this guidance.[54]

40. Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026

In accordance with section 1193(a) of the Act, the Secretary shall enter into agreements with manufacturers of selected drugs. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" of the selected drug (hereinafter "Primary Manufacturer").

Likewise, for initial price applicability year 2026, CMS will refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on the NDA or BLA as a "Secondary Manufacturer." A Secondary Manufacturer will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meet these criteria. A manufacturer that is not listed as a manufacturer on the NDA / BLA and without an agreement in place with the Primary Manufacturer would not be considered a Secondary Manufacturer.

In the example described in section 30.1 of this revised guidance, if the potential qualifying single source drug described was selected for negotiation, entity "A" would be considered the Primary Manufacturer while entity "B" would be considered a Secondary Manufacturer either because it was listed as a manufacturer in NDA-1 or if it was not listed as a manufacturer in NDA-1 because it markets the three strengths of the immediate release tablets manufactured by entity A pursuant to an agreement with entity A.

CMS will sign an agreement (a "Medicare Drug Price Negotiation Program Agreement," herein referred to as an "Agreement") with the willing Primary Manufacturer of each selected drug and believes this approach aligns with the statute's requirement to negotiate to determine an MFP with "the manufacturer" of a selected drug in accordance with section 1193(a) of the Act. This Agreement, as described in this section 40, will set forth requirements of the Primary Manufacturer with respect to its participation in the Negotiation Program, including with respect to section 1193(a)(5) of the Act, which requires the Primary Manufacturer to comply with

[53] CMS acknowledges that, for some selected drugs, the list of NDC-9s and NDC-11s might not reflect all NDCs marketed pursuant to the approved NDA(s) / BLA(s). For example, if a selected drug includes one NDC-9 that has no current or future Part D PDE utilization (e.g., the NDC-9 is utilized only in Part B settings of care), that NDC-9 and associated NDC-11s would not be included on the published list of NDC-9s and NDC-11s of the selected drug for initial price applicability year 2026.

[54] See: https://www.cms.gov/inflation-reduction-act-and-medicare.

requirements set forth in this revised guidance, which CMS has determined are necessary for purposes of administering and monitoring compliance with the Negotiation Program.

CMS will not enter into an Agreement with any Secondary Manufacturer of a selected drug with respect to that drug. As such, under section 1193(a)(4), a Primary Manufacturer that enters into an Agreement must collect and report necessary information applicable to any Secondary Manufacturer(s) as described in section 40.2 of this revised guidance. As the entity that is party to the Agreement, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Agreement and will be accountable for ensuring compliance with respect to units of the selected drug manufactured by the Secondary Manufacturer or marketed by any Secondary Manufacturer pursuant to an agreement with the Primary Manufacturer. In accordance with section 1193(a)(1) of the Act and section 40.4 of this revised guidance, the Primary Manufacturer must ensure that any Secondary Manufacturer(s) make the MFP available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers. For initial price applicability year 2026, the scope of Primary Manufacturer responsibility to provide access to the MFP for the selected drug is limited to units of such drug sold by the Primary Manufacturer or a Secondary Manufacturer. CMS reiterates that the requirement for Primary Manufacturers to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as described in section 80 of this revised guidance. Failure to comply with obligations to make the MFP available may result in civil monetary penalties being assessed on the Primary Manufacturer pursuant to section 1197(a) of the Act.

CMS requires that for initial price applicability year 2026, the Primary Manufacturer of a selected drug is the entity that does each of the following:

1. Signs the Agreement with CMS, as described in section 40.1 of this revised guidance;
2. Collects and reports all data required for negotiation under section 1193(a)(4) of the Act, including the negotiation data elements, as described in section 40.2, section 50.1, and Appendix C of this revised guidance;
3. Negotiates an MFP with CMS, as described in section 40.3 of this revised guidance;
4. Ensures the MFP is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that dispense the selected drug to those individuals, as described in section 40.4 of this revised guidance; and
5. Responds to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities, and pays any CMPs for violations, including: violating the terms of the Agreement; providing false information under the procedures to apply the aggregation rule for the Small Biotech Exception or the Biosimilar Delay; failing to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but which has since undergone negotiation as described in section 1192(f)(4) of the Act; or not providing access to the MFP to MFP-eligible individuals, pharmacies, mail order services, and other dispensers, as described in section 40.5, section 90, and section 100 of this revised guidance.

Termination of an Agreement for the Negotiation Program is described in section 40.6 of this revised guidance, and other relevant provisions from the Agreement are described in section 40.7. of this revised guidance.

40.1 Entrance into an Agreement with CMS and Alternatives

Section 1193(a) of the Act instructs CMS to enter into agreements with manufacturers of selected drugs for a price applicability period. The deadline for the Primary Manufacturer of a selected drug to enter into an Agreement for initial price applicability year 2026 is October 1, 2023. The Primary Manufacturer must use the CMS HPMS to identify relevant authorized representative(s) and effectuate the Agreement.[55]

CMS recommends, but does not require, that within five days following publication by CMS on September 1, 2023 of the list of selected drugs for an initial price applicability year, the Primary Manufacturer submit to CMS the name(s), title(s), and contact information for the representative(s) authorized to execute the Agreement. CMS recommends taking this action as soon as possible to facilitate timely communication and effectuation of the Agreement. The authorized representative(s) must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Agreement, including any Addenda. The authorized representatives should follow instructions made available on the CMS HPMS webpage to gain access to the CMS HPMS. To be eligible for electronic signature access in CMS HPMS, an authorized representative must be the Primary Manufacturer's Chief Executive Officer, Chief Financial Officer, an individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer, or an individual that has been granted direct delegated authority to perform electronic signatures on behalf of one of the individuals previously noted. CMS notes that it is a requirement of the CMS HPMS that the person accessing the CMS HPMS have a Social Security Number (SSN). An authorized representative of the Primary Manufacturer must access the CMS HPMS and sign the Agreement by October 1, 2023.

The negotiation period for initial price applicability year 2026 will begin on the earlier of two dates: the date on which the Agreement is executed (i.e., signed by both CMS and the Primary Manufacturer) or October 1, 2023. If an Agreement is fully executed before October 1, 2023, the negotiation period (as defined in section 1191(b)(4) of the Act) will begin on the date on which the Agreement is signed by the last party to sign it. If the Agreement is not fully executed by October 1, 2023, then pursuant to 26 U.S.C. § 5000D(b)(1), a period will begin on October 2, 2023, during which the manufacturer could be exposed to potential excise tax liability. CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list for initial price applicability year 2026 is published.

Section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program. If a Primary Manufacturer decides it is unwilling to enter into an Agreement for the Negotiation Program, it may expedite its exit from the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program by submitting to CMS a notice that incorporates both: (1) a notice of decision not to participate in the Negotiation Program; and

[55] See: https://hpms.cms.gov/app/ng/home/.

(2) a request for termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program. When a Primary Manufacturer submits such a notice, CMS will find good cause to terminate the Primary Manufacturer's agreement(s) under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14A(b)(4)(B)(i) and section 1860D-14C(b)(4)(B)(i) of the Act to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under section 1860D-14A or section 1860D-14C. CMS has determined (and hereby provides notice) that it will automatically grant such termination requests upon receipt, and that it will expedite the effective date of the Primary Manufacturer's termination of its Medicare Coverage Gap Discount Program and/or Manufacturer Discount Program agreements consistent with the statutory limitation that termination shall not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination.

If a Primary Manufacturer has determined it would not be willing to enter into an Agreement for the Negotiation Program if one of its drugs is listed as a selected drug and has submitted a notice of its decision and its request for termination as described above, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning its termination request. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its termination request.

40.2 Submission of Manufacturer Data to Inform Negotiation

After entering into an Agreement with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug must submit to CMS the following information with respect to the selected drug: information on the non-Federal average manufacturer price ("non-FAMP") (defined in section 8126(h)(5) of title 38, United States Code), as described in section 50.1.1 and Appendix C of this revised guidance, and any information that CMS requires to carry out negotiation, including but not limited to the factors listed in section 1194(e)(1) of the Act, as described in section 50.1 and Appendix C of this revised guidance. This information must be submitted by the Primary Manufacturer to CMS no later than October 2, 2023, for initial price applicability year 2026.

The Agreement must be fully executed, meaning both the Primary Manufacturer and CMS have signed the Agreement, before the Primary Manufacturer may submit the data elements described in this section. While these data elements may not be submitted prior to execution of the Agreement, Primary Manufacturers will be able to access the data elements template in the CMS HPMS, and CMS believes Primary Manufacturers will be able to gather these data prior to the Agreement being executed. By signing the Agreement, a Primary Manufacturer agrees to use the CMS HPMS and comply with all relevant procedures and policies set forth in the CMS HPMS for utilizing the system.

Certain data, as described in section 50.1 and Appendix C of this revised guidance, must reflect any products included in the selected drug marketed by a Secondary Manufacturer(s), and the Primary Manufacturer is responsible for collecting such data from such Secondary Manufacturer(s) and including this information in its submission to CMS.

For each selected drug for initial price applicability year 2026, CMS will populate the CMS HPMS with the list of the NDC-11s published in accordance with section 30.4 of this revised guidance, meaning those NDC-11s of the selected drug that either had Part D PDE utilization in the 12-month period beginning June 1, 2022 and ending May 31, 2023 or which CMS believes are likely to have PDE utilization in the future (for example, NDC-11s associated with recently approved NDAs / BLAs). This list will include any NDC-11s of the selected drug marketed by the Primary Manufacturer and any Secondary Manufacturer. CMS will transmit the list to the Primary Manufacturer of the selected drug. In connection with the data submission described in section 50.1 of this revised guidance, the Primary Manufacturer must provide CMS with information regarding the NDC-11s that may be appropriate to ensure the list is complete and accurate, including but not limited to, whether any NDC-11s associated with the NDA(s) / BLA(s) of the selected drug are missing from the list (e.g., because they are new NDC-11s), including any missing NDC-11s of a Secondary Manufacturer of the selected drug; whether any of the listed NDC-11s are marketed or controlled solely by a manufacturer that is not the Primary Manufacturer or a Secondary Manufacturer; and whether any of the listed NDC-11s have been discontinued. CMS will collect this information in the CMS HPMS as part of the collection of the other data elements described in section 50.1 of this revised guidance and update this list as necessary (e.g., based on supplements from the Primary Manufacturer or other updates).

This list of NDC-11s constitutes the baseline of NDCs of the selected drug as described in section 30 of this revised guidance that will be subject to the negotiation process for initial price applicability year 2026. The NDC-11s on this list will be included in ceiling calculations for initial price applicability year 2026 as described in section 60.2, to the extent data are available to support such calculations. CMS will also use the NDC-11s on this list for the calculations used to apply the MFP across dosage forms and strengths of the selected drug for initial price applicability year 2026 as described in section 60.5 of this revised guidance. In addition, CMS will use the information supplied by the Primary Manufacturer about discontinued NDC-11s as additional context for the data elements described in section 50.1 of this revised guidance (e.g., notice that an NDC-11 has been discontinued may explain why a Primary Manufacturer submitted partial year data for a particular NDC-11 of a selected drug).

The Primary Manufacturer has an ongoing obligation to timely report any changes in this information to ensure the list of NDC-11s of the selected drug in the CMS HPMS remains complete and accurate consistent with this revised guidance and any future guidance and regulations. For example, a Primary Manufacturer must report to CMS any new NDC-11s of the selected drug at least 30 days prior to their first marketed date for any Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug; if CMS believes these new NDC-11s are likely to have PDE utilization in the future, these NDC-11s will be added to the list of NDC-11s of the selected drug. The Primary Manufacturer also must report to CMS the delisting of any NDC-11 of the selected drug that is no longer marketed by the Primary Manufacturer or any

Secondary Manufacturer(s) within 30 days after its discontinuation. Failure of the Primary Manufacturer to provide timely information material to the accuracy of the list of NDC-11s of the selected drug as described in this section 40.2 of the revised guidance will be considered a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to civil monetary penalties per section 1197(c) of the Act.

40.2.1 Confidentiality of Proprietary Information

Section 1193(c) of the Act states that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secrets and confidential commercial or financial information, will also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).[56]

CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary. Thus, for initial price applicability year 2026, CMS will treat information on non-FAMP as proprietary.

For initial price applicability year 2026, CMS will also treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section 1194(e)(2) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. Specifically, CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS understands these data are publicly available.

Pursuant to section 1195(a)(2) of the Act, CMS is required to publish the explanation of the MFP by March 1, 2025, for initial price applicability year 2026 (see section 60.6.1 of this revised guidance). In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer and the public that are determined to be non-proprietary, but will not include any protected health information (PHI) or personally identifiable information (PII). CMS will also make public high-level comments about the section 1194(e)(1) and section 1194(e)(2) data submitted to CMS that are determined to be proprietary, without sharing any PHI / PII or any proprietary information reported to CMS under section 1193(a)(4) for purposes of the negotiation. For example, CMS will not make public the research and development costs

[56] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may say "the manufacturer has recouped its research and development costs." Any proprietary information obtained during the course of an audit will also remain confidential, except as necessary to use that information in the course of a judicial enforcement proceeding.

40.2.2 Data and Information Use Provisions and Limitations

CMS will not publicly discuss ongoing negotiations with a Primary Manufacturer, except as outlined below. As described in section 60.6.1, CMS will make public a narrative explanation of the negotiation process and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable.

Primary Manufacturers may choose to publicly disclose information regarding its ongoing negotiations with CMS at its discretion. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this guidance. For example, if a Primary Manufacturer chooses to publicly disclose the unit cost of production, CMS will no longer consider the unit cost of production to be proprietary. If the Primary Manufacturer chooses to disclose proprietary information prior to the explanation of the MFP, then it will not be redacted in the explanation of the MFP. Primary Manufacturers negotiating an MFP with CMS pursuant to the process set forth in section 60 are reminded that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. Information exchanges concerning confidential and strategic business negotiations may violate the antitrust laws under certain circumstances and lead to other anticompetitive agreements. Primary Manufacturers should consider the antitrust implications of any such actions.

CMS will prohibit audio or video recording of any negotiation meetings between CMS and a Primary Manufacturer. CMS will maintain written records of the negotiation process, including negotiation meetings, in compliance with applicable federal law, including the Federal Managers Financial Integrity Act and the Federal Records Act. A Primary Manufacturer can maintain its own written record of these exchanges.

40.2.3 Opportunity for Corrective Action Following Information Submission

Recognizing the substantial role that manufacturer-submitted information will play in the negotiation process and in administering and monitoring the Negotiation Program, CMS will provide an opportunity for corrective action in the event a submission is incomplete or inaccurate. Upon receipt of Primary Manufacturer-submitted information – for example, information on the section 1194(e)(1) factors – CMS will review the submission for completeness and accuracy. Should CMS determine a submission is incomplete or contains inaccurate information, CMS will provide a written request that the Primary Manufacturer take corrective action and resubmit the information. CMS will provide five business days for the Primary Manufacturer to correct the submission and/or provide additional information to validate

the accuracy/completeness of the original submission. Following resubmission, CMS may follow up with the Primary Manufacturer to clarify any information included in the resubmission and confirm full accuracy and completeness of the required information.

To facilitate the corrective action process, CMS will provide the Primary Manufacturer with a written request for the corrected information, which will be transmitted to the Primary Manufacturer following CMS' discovery of any inaccurate or incomplete submissions. The written request will include a deadline for resubmitting the information (i.e., the end of the five-business day period). CMS will make efforts to be available to engage with the Primary Manufacturer about the specifics of the request for corrected information and to answer questions and provide clarification. Note that failure to engage in timely corrective action may result in the Primary Manufacturer being subject to civil monetary penalties as authorized under section 1197(c) for failure to submit required information.

40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years

CMS will use the CMS HPMS to share the initial offer and concise justification, any subsequent offer and justification, and to receive any counteroffer(s) from the Primary Manufacturer of a selected drug. A Primary Manufacturer that signs the Agreement will be required to adhere to the process and deadlines described in section 60 of this revised guidance. CMS will also use the CMS HPMS to share and receive an Addendum to the Agreement, as applicable, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP that results from the negotiation process. For example, concurrent with the agency's provision of the initial offer, CMS will populate an Addendum in the CMS HPMS containing the MFP identified in the initial offer; if a Primary Manufacturer wishes to accept CMS' initial offer, it can sign the Addendum in the CMS HPMS. Similarly, concurrent with the Primary Manufacturer's submission of a written counteroffer, the Primary Manufacturer will populate an Addendum in the CMS HPMS containing the MFP identified in the counteroffer and sign the Addendum; if CMS wishes to accept the counteroffer, it will countersign the Addendum in the CMS HPMS. CMS will determine that negotiations have concluded upon execution by both parties of the Addendum setting forth the agreed-upon MFP.

Pursuant to section 1194(f) of the Act, CMS and a Primary Manufacturer may renegotiate the MFP for a selected drug, beginning with 2028. CMS plans to release guidance related to the renegotiation process in future years.

40.4 Providing Access to the MFP

After entering into an Agreement with CMS and in accordance with section 1193(a) of the Act, the manufacturer of a selected drug must provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act and section 80 of this revised guidance) and to pharmacies, mail order services, and other dispensers with respect to such MFP-eligible individuals who are dispensed that drug during a price applicability period. That is, the manufacturer is required to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug (i.e., NDCs included in the MFP file published in accordance with section 60.6 of this revised guidance), including any additional such dosage forms, strengths, and package sizes that may be further included in the MFP file, if coverage is being provided for such dosage forms, strengths, and package sizes under a prescription drug plan

under Medicare Part D or an MA–PD plan under Medicare Part C (including an Employer Group Waiver Plan).

Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the MFP plus any dispensing fees for such drug. In Part D, the negotiated price of a drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point of sale. Therefore, the requirement that the price used for beneficiary cost-sharing and benefit administration cannot exceed the MFP (plus dispensing fees) helps to ensure that Part D MFP-eligible individuals will have access to the MFP at the point of sale. Therefore, while section 1193(a) of the Act requires manufacturers to provide access to the MFP to MFP-eligible individuals, as a practical matter, this would be facilitated by Part D plan sponsors in the normal course.

However, section 1193(a) of the Act also requires that the manufacturer of a selected drug provide access to the MFP for the selected drug to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed such drugs. CMS requires that the Primary Manufacturer ensures that entities that dispense drugs to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers, have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further described in section 90.2 of this revised guidance. CMS defines "providing access to the MFP" as ensuring that the amount paid by the dispensing entity for the selected drug is no greater than the MFP.

Primary Manufacturers must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. As part of this obligation, the Primary Manufacturer must ensure the MFP is made available to pharmacies, mail order services, and other dispensers for units of the selected drug for which there is a Secondary Manufacturer. With respect to the second option, CMS plans to issue further information regarding the specific calculation that the manufacturer could use in the determination of the refund to the dispenser. CMS is exploring whether manufacturers could offer a standardized refund amount, such as the Wholesale Acquisition Cost (WAC) of the selected drug minus the MFP (WAC-MFP), in order to meet this obligation.

CMS intends to engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between pharmaceutical supply chain entities to support the verification of an MFP-eligible individual who is dispensed a selected drug. CMS intends to continue to work with interested parties to identify existing processes and any new processes that would be the most viable for the supply chain to operationalize to ensure that pharmacies, mail order services, and other dispensers have access to the MFP during the price applicability period. CMS will consult with pharmacies, mail order services, and other dispensers, as well as with industry standard development organizations (SDOs), 340B covered entities and related organizations, pharmaceutical/biotechnology manufacturers, and other supply chain participants to understand existing data flows and identify opportunities for increased connectivity and data sharing. CMS is also exploring options to facilitate retrospective payment exchange between manufacturers and

dispensing entities to help effectuate access to the MFP. CMS plans to release more information in advance of initial price applicability year 2026 regarding such issues related to ensuring access to the MFP, including how CMS might support and facilitate data exchange between pharmaceutical supply chain entities.

A Primary Manufacturer must ensure that pharmacies, mail order services, and other dispensers are reimbursed timely. That is, CMS requires that the MFP must be passed through to the dispensers within 14 days of the manufacturer receiving sufficient information to verify that an individual is eligible for access to the MFP. Neither Primary Manufacturers nor their contracted entities shall charge any transaction fees for the data exchanges that would be facilitated through an MTF. Regardless of whether existing processes or new processes are used to facilitate access to the MFP, manufacturers are expected to comply with existing applicable data privacy and security laws. Primary Manufacturers must work with any Secondary Manufacturer of a selected drug to determine how the MFP will be passed through in a manner that complies with applicable data privacy and security laws.

Further, CMS requires that a Primary Manufacturer submit its process for making the MFP available, including to 340B covered entities, for the selected drug in writing to CMS at least 30 days before the start of the initial price applicability year for the selected drug. CMS intends to publish these processes on the CMS IRA website. For initial price applicability year 2026, a Primary Manufacturer of a selected drug must send its process for ensuring MFP availability to CMS in writing by December 2, 2025. A Primary Manufacturer must notify CMS of any changes to its process for making the MFP available at least 30 days before the change goes into effect. CMS will monitor for compliance, and will audit as needed, to ensure that the MFP is being made available for the selected drug (see section 90.2 of this revised guidance for additional details). A Primary Manufacturer must retain for at least ten years from the date of sale any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers for units of selected drug, in alignment with the statute of limitations period under the False Claims Act.

CMS notes that the Agreement would not restrict the Primary Manufacturer or Secondary Manufacturer(s) from offering to the Part D plans a price lower than the MFP that would be passed through to the beneficiary by the dispenser. CMS reiterates that Primary Manufacturers are responsible for ensuring that the MFP is made available to pharmacies, mail order services, and other dispensers that dispense the selected drug to MFP-eligible individuals, including ensuring that MFP is available for units of the selected drug for which there is a Secondary Manufacturer. Commercial and other payers will continue to have discretion to consider Medicare payment rates among other considerations in establishing their own payment policies.

40.4.1 Nonduplication with 340B Ceiling Price

In accordance with 1193(d) of the Act and as further described in section 90.2 of this revised guidance, the Primary Manufacturer of a selected drug is not required to provide access to the MFP for a selected drug to MFP-eligible individuals who are eligible to be dispensed such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B

ceiling price (defined in section 340B(a)(1) of the PHS Act) is lower than the MFP for such selected drug.

A manufacturer that provides an MFP on a selected drug is not also required to provide a 340B discount on that same drug. That is, these price concessions are not cumulative. CMS expects that the ingredient cost component of all Part D prescriptions filled for a selected drug will be no greater than the drug's MFP, including when those prescriptions are filled at 340B covered entities and their contract pharmacies. CMS understands that 340B covered entities and their contract pharmacies currently use different inventory management processes for 340B drugs, such as separate physical drug inventories or a retrospective replenishment model. Regardless of the specific inventory management process used, the same policies regarding the MFP will apply, including that the manufacturer must provide access to the lower of the MFP or 340B ceiling price, such as through a replenished 340B inventory or an MFP refund within 14 days of determining that the selected drug was dispensed to an MFP-eligible individual.

CMS intends to work with the Health Resources and Services Administration, which administers the 340B Drug Pricing Program, to help to ensure that the MFP is made available to 340B covered entities where appropriate and that there is no duplication with the 340B ceiling price.

40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

Pursuant to CMS' statutory obligation under sections 1191(a)(4), 1196, and 1197 of the Act, CMS will establish a robust program for monitoring compliance with the Negotiation Program. After entering into an Agreement with CMS and in accordance with section 1193(a)(5) of the Act, the Primary Manufacturer must comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program. For example, CMS anticipates engaging in auditing processes to verify the accuracy and completeness of any information provided by the Primary Manufacturer under the requirements of section 1193(a)(4) of the Act. CMS also may audit any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by a Secondary Manufacturer. CMS will document all requests for information required to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. Written requests from CMS to the Primary Manufacturer will include a date by which the requested information shall be submitted to CMS. If the Primary Manufacturer fails to submit complete and accurate information to CMS by the deadline stated in a request for information, CMS will consider the Primary Manufacturer in violation of the Agreement and the Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act.

CMS will allow a Primary Manufacturer that believes in good faith that CMS has made an error in the calculation of the ceiling or the computation of how CMS will apply a single MFP across dosage forms and strengths to submit a suggestion of error for CMS' consideration. As feasible, CMS will provide information on these calculations to the Primary Manufacturer within 60 days of the Primary Manufacturer's submission of data that complies with the requirements described in section 50.1. A Primary Manufacturer will have 30 days to submit a suggestion of error and may do so by submitting the request via email to IRARebateandNegotiation@cms.hhs.gov with

the subject line "Suggestion of Error for [name of the selected drug]." This notification should include supporting information documenting why the Primary Manufacturer believes that CMS made a mathematical error in its calculations and corresponding steps that should be reviewed. CMS will review and respond within 30 days of receiving the suggestion of error from the Primary Manufacturer if feasible. The suggestion of error process does not imply that a Primary Manufacturer need not comply with Negotiation Program requirements and will not affect any timelines or requirements of the Negotiation Program.

40.6 Termination of the Agreement

In accordance with section 1193(b) of the Act, when the Primary Manufacturer enters into the Agreement described in section 40.1 of this revised guidance, the Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer considered a selected drug under section 1192(c) of the Act as described in section 70 of this revised guidance unless the Agreement is terminated sooner by the Primary Manufacturer under the conditions specified below. Accordingly, the Agreement will have an effective date as of the date the Agreement is signed by both parties (the "Effective Date"), and the term of the Agreement will be from the Effective Date of the Agreement to the earlier of the first year that begins at least 9 months after the date on which CMS determines that the selected drug is no longer a selected drug under section 1192(c) of the Act or the Agreement is terminated by either party in accordance with this section (the "Termination Date").

In accordance with section 1193(a)(5) of the Act, a Primary Manufacturer may terminate its Agreement with respect to a selected drug with respect to a price applicability period, before reaching an agreement with CMS as to the MFP for the selected drug or after such an MFP is agreed to, if the Primary Manufacturer meets certain conditions for termination consistent with the provisions in 26 U.S.C. § 5000D(c). Specifically, a Primary Manufacturer seeking to terminate its Agreement with respect to a selected drug must submit to CMS a notice of request to terminate. As noted in section 40.1, section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program and the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program. The provisions enacted at 26 U.S.C. § 5000D give the Primary Manufacturer choices with regard to the Negotiation Program. The Primary Manufacturer may participate in the Negotiation Program. The Primary Manufacturer may opt out of the Negotiation Program and pay the excise tax on the sale of the selected drug during defined periods. Alternatively, the Primary Manufacturer may opt out of the Negotiation Program and avoid the excise tax on sales of the selected drug during the period for which the manufacturer does not have applicable agreements with the Medicare and Medicaid programs and none of its drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act. Promoting continuity in the administration of the Negotiation Program warrants extending parallel options to a Primary Manufacturer with respect to potential CMP liability. A Primary Manufacturer with an Agreement with respect to the price applicability period with respect to a selected drug may opt out of the Negotiation Program and pay CMPs associated with violations of program requirements. Alternatively, a Primary Manufacturer seeking to cease participation in the Negotiation Program through the end of the price applicability period for a selected drug may avoid CMP liability by terminating its Agreement if it also ceases participation in the Medicaid Drug Rebate Program and the Medicare

Coverage Gap Discount Program and the Manufacturer Discount Program through the end of the price applicability period for the selected drug.

Thus, in accordance with section 1193(a)(5) of the Act, CMS has determined that the Primary Manufacturer's notice of termination of the Agreement must incorporate both (1) a request for termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program and the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. § 5000D(c)(1)(A)(i), and (2) an attestation that through the end of the price applicability period for the selected drug, the Manufacturer (a) shall not seek to enter into any subsequent agreement with any such program and (b) shall not seek coverage for any of its drugs under the Medicare Coverage Gap Discount Program under section 1860D-14A of the Act or the Manufacturer Discount Program under section 1860D-14C of the Act, consistent with the requirements as set forth in 26 U.S.C. § 5000D(c)(1)(B). A Primary Manufacturer later seeking to re-enter any applicable agreement or obtain coverage for any of its drugs under the Medicare Coverage Gap Discount Program or the Manufacturer Discount Program would be deemed to have provided an invalid attestation that was a condition of termination, and the Agreement would once again become operative as of the date of re-entry into the applicable agreements or coverage for any of its drugs under the Medicare Coverage Gap Discount Program or the Manufacturer Discount Program. If a Primary Manufacturer terminated its Agreement prior to completing the negotiation process and agreeing to an MFP, such process will be initiated or resumed in accordance with the negotiation process described in section 60 of this revised guidance. In addition, the timing of the Primary Manufacturer's decision to resume participation in the Negotiation Program may implicate the renegotiation process beginning with 2028, for which guidance will be forthcoming for future years of the Negotiation Program.

If the conditions for termination of the Agreement for the Negotiation Program described above are met, CMS will terminate such Agreement effective on the first date on which the notices of termination for all applicable agreements have been received and none of the drugs of the Primary Manufacturer are covered by an agreement under the Medicare Coverage Gap Discount Program or the Manufacturer Discount Program. As is noted above, section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program and the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program. If a Primary Manufacturer determines after executing its Agreement that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice that complies with the requirements in this section 40.6, CMS will find good cause to terminate the Primary Manufacturer's agreement(s) under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14A(b)(4)(B)(i) and section 1860D-14C(b)(4)(B)(i) of the Act to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under section 1860D-14A or section 1860D-14C and thus facilitate an expedited Termination Date.

Moreover, consistent with the process described in Section 40.1 above, if a Primary Manufacturer has determined it is unwilling to continue its participation in the Negotiation Program and provides a termination notice that complies with the requirements in this section

40.6, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning its termination request for its applicable agreements under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its termination request.

Notwithstanding any termination of the Agreement, the MFP shall continue to apply for any selected drugs that were dispensed prior to the Termination Date. Also, notwithstanding the termination of the Agreement, any confidentiality, record retention, and/or data requirements and any requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities shall continue to apply.

40.7 Other Provisions in the Agreement

Additional terms in the Agreement set forth general provisions in accordance with requirements determined by CMS to be necessary for purposes of administering or monitoring compliance with the Negotiation Program. For example, any notice required to be given by the manufacturer or CMS must be sent in writing via email to CMS- and manufacturer-designated email addresses. CMS retains the authority to amend the Agreement to reflect changes in law, regulation, or guidance, and, when possible, CMS will give the Manufacturer at least 60-day notice of any change to the Agreement.

In accordance with section 1193(a)(5) of the Act, if, after entering in an Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs / BLAs of the selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Agreement, including the requirement to provide access to the MFP, associated with the transferred NDAs / BLAs unless and until the Primary Manufacturer transfers all the NDAs / BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer. Those steps must be evidenced by a novation to the transferring Primary Manufacturer's original Agreement for the Negotiation Program. The transferring Primary Manufacturer remains responsible for any outstanding Negotiation Program rebate liabilities related to the biosimilar delay provision under section 1192(f) of the Act unless and until such liabilities are transferred to the acquiring entity as the new Primary Manufacturer. The transferring Primary Manufacturer shall provide CMS at least 30 calendar days written notice before the effective date of any such transfer and, if applicable, any novation.

If the Primary Manufacturer of a selected drug transfers all NDAs / BLAs of the selected drug pursuant to the preceding paragraph, such that an acquiring entity assumes responsibility as the new Primary Manufacturer of the selected drug for purposes of the Negotiation Program, CMS recognizes that this transfer of ownership could affect the Primary Manufacturer's potential excise tax liability as well as the impact on the Primary Manufacturer of the statutory suspension

of excise tax provisions and the termination process as described in section 40.6 of this revised guidance. CMS recognizes that whether this transfer of ownership would have these impacts would depend on whether the transfer of the NDAs / BLAs was made to an entity that is not a related party (e.g., not treated as part of the same employer under subsections (a) and (b) of section 52 of the Internal Revenue Code of 1986) and complied with relevant principles of tax law.

If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if the invalid or unenforceable provision(s) were eliminated, and without any effect on any other provisions.

50. Negotiation Factors

In accordance with sections 1193(a)(4) and 1194(b)(2)(A) of the Act, the Primary Manufacturer of a selected drug that has chosen to sign the Agreement must submit, in a form and manner specified by CMS, information on the non-FAMP for the selected drug (described in section 50.1.1 of this revised guidance). The Primary Manufacturer must also submit information on certain factors (described in section 1194(e)(1) of the Act and described further in section 50.1 of this revised guidance). The Primary Manufacturer will be responsible for aggregating and reporting information from any applicable Secondary Manufacturer(s). In addition, the statute prescribes that CMS also consider available evidence about therapeutic alternatives to the selected drug(s) (described in section 1194(e)(2) of the Act and described further in section 50.2 of this revised guidance).

While the statute requires that CMS consider manufacturer-specific data for the factors described at section 1194(e)(1) of the Act, the statute does not specify what sources CMS must use for the factors described at section 1194(e)(2) regarding therapeutic alternatives to a selected drug. CMS will consider evidence about therapeutic alternatives relevant to the factors described in section 1194(e)(2) of the Act submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties. CMS believes that by allowing any interested party to submit data, CMS will be best positioned to identify all available, relevant evidence for the factors described at section 1194(e)(2).

CMS published the Negotiation Data Elements ICR in the Federal Register on March 21, 2023. The Negotiation Data Elements ICR describes how CMS will collect the data outlined in sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act. This ICR includes instructions on how Primary Manufacturers and members of the public may submit relevant data. The comment period for the Negotiation Data Elements ICR closed on May 22, 2023. CMS is releasing a revised version of the Negotiation Data Elements ICR on June 30, 2023, and the 30-day comment period will close on July 31, 2023.

The definitions that CMS is adopting for the purposes of describing the data to be collected for use in the Negotiation Program under sections 1193(a)(4)(A) and 1194(e)(1) of the Act are specified in Appendix C of this revised guidance.

In accordance with sections 1191(d)(5)(A), 1194(b)(2)(A), and 1193(a)(4)(B) of the Act, the data described in sections 50.1 and 50.2 of this revised guidance for drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023. CMS' determination to

require public submission on the same date as manufacturer submission (i.e., October 2, 2023) serves to enable CMS to consider all submitted evidence in totality and meet the statutory deadline for the initial offer, pursuant to general program administration authority.

50.1 Manufacturer-Specific Data

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers, as described in section 60 of this revised guidance. These factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Submission of these data by the Primary Manufacturer is required if an Agreement is signed; details related to the submission process are described in section 40.2 of this revised guidance.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by October 2, 2023:

1. Research and development (R&D) costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
3. Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s).

The Primary Manufacturer should submit information in the CMS HPMS for the NDC-11s of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to section 40.2 of this revised guidance. As noted above, CMS requires the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-FAMP, current unit costs of production and distribution, and certain data pertaining to market data and revenue and sales volume data for the selected drug.

Please see Appendix C of this revised guidance for a list of definitions that apply for purposes of describing these data to be collected for use in the Negotiation Program.

50.1.1 Non-FAMP Data

The Primary Manufacturer must submit data on non-FAMP for the selected drug for the Primary Manufacturer and any Secondary Manufacturer(s), as required under section 1193(a)(4)(A) of the Act. CMS will be collecting these data through the Negotiation Data Elements ICR described above. Specifically, for initial price applicability year 2026, the Primary Manufacturer must submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar year 2021, or in the case that there is not an average non-FAMP price available for such drug for 2021, the non-FAMP, unit type, and total unit volume for each

NDC-11 of the selected drug for the four quarters of the first full calendar year following market entry of such drug. For purposes of determining the applicable year, CMS will consider the average non-FAMP price to be available for a selected drug for calendar year 2021 if the Primary Manufacturer reports at least one quarter of non-FAMP data for at least one NDC-11 of the selected drug in calendar year 2021. As described in Appendix C, when there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) for a given NDC-11 of such drug, the non-FAMP reported by the manufacturer to CMS for that calendar quarter should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price as described in the Department of Veterans Affairs' (VA) 2023 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585. Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS. The use of these data to calculate the ceiling for the MFP is further described in section 60.2 of this revised guidance. Details on how CMS defines the parameters of the non-FAMP data collection are included in Appendix C of this revised guidance and are also included in the Negotiation Data Elements ICR.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

As noted above, section 1194(e)(2) of the Act directs CMS to consider evidence about alternative treatments to the selected drug, as available, including:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, herein referred to as "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Section 1194(e)(2) of the Act additionally requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Information submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties, or other information found by CMS that treats extending the life of individuals in these populations as of lower value will not be used in the Negotiation Program.[57]

[57] Some uses of QALY treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. CMS will not use any QALY in the Negotiation Program.

CMS will review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the measure used is permitted in accordance with section 1194(e)(2), as well as with section 1182(e) of Title XI of the Act. CMS may use content in a study that uses a cost effectiveness-measure if it determines that the cost-effectiveness measure used is permitted in accordance with the law and does not treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. In instances where some, but not all, content in a study is excluded (e.g., QALYs), CMS may still consider content that is relevant and allowable (e.g., clinical effectiveness, risks, harms) under section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act. CMS requires respondents submitting information to indicate whether their submission contains information from studies that use measures that treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. CMS also requests that respondents submitting information under 1194(e)(2) provide a short description of any cost-effectiveness measures included in the research they are submitting, and how they believe the data avoids treating extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

The Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties, may submit information on selected drugs and their therapeutic alternatives (specifically pharmaceutical therapeutic alternatives, as described in detail in section 60.3.1 of this revised guidance), including information on whether the selected drug represents a therapeutic advance over its therapeutic alternative(s), prescribing information for the selected drug and its therapeutic alternative(s), comparative effectiveness data for the selected drug and its therapeutic alternative(s), information about the impact of the selected drug and its therapeutic alternative(s) on specific populations, information about patient experience, and/or information on whether the selected drug addresses unmet medical need, as described in section 1194(e)(2) of the Act. Outcomes such as changes to productivity, independence, and quality of life will also be considered when these outcomes correspond with a direct impact on the individuals taking the selected drug or therapeutic alternative and are appropriately measurable and quantifiable.

CMS will additionally review existing literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts on these topics (described in section 60.3.1 of this revised guidance) when considering available evidence about alternative treatments to the selected drug. When reviewing the literature from the public and manufacturer submissions as well as literature from CMS' review, CMS will consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. CMS will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., has sufficient sample size) to answer the primary question

of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses.

CMS will consider research and real-world evidence relating to Medicare populations, including on individuals with disabilities, patients with end-stage renal disease (ESRD), and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, CMS will prioritize research specifically designed to focus on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus.

All information on the factors described in section 1194(e)(2) of the Act related to drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023.

Please see Appendix C of this revised guidance for a list of definitions that CMS adopted for the purposes of describing these data to be collected for use in the Negotiation Program.

60. Negotiation Process

In accordance with section 1194(b)(1) of the Act, CMS will develop and use a consistent methodology and process for negotiation with the aim of achieving agreement on "the lowest maximum fair price for each selected drug." This section 60 describes the negotiation process, including the development of the written initial offer, the process for making such offer and providing a concise justification to the Primary Manufacturer of a selected drug, the process and requirements for accepting an offer or providing a counteroffer, the potential for up to three negotiation meetings between CMS and the Primary Manufacturer, the conclusion of negotiation, the publication of the MFP, and explanation of the MFP.

60.1 Establishment of a Single MFP for Negotiation Purposes

In accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b), as applicable, for such drug and year. CMS interprets this language to refer to negotiation of a single price for a selected drug with respect to its price applicability period. Accordingly, CMS will identify a single price for use at each step in the negotiation process described in this section 60, meaning each offer and counteroffer, described in section 60.4 of this revised guidance, will include a single price, even for a selected drug with multiple dosage forms and strengths. Once the MFP has been agreed upon, section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply the MFP across different dosage forms and strengths of a selected drug.

For the purposes of determining a single price included in an initial offer (including evaluating clinical benefit compared to the therapeutic alternative(s), as described in section 60.3 of this revised guidance) and conducting the negotiation, CMS will base the single price on the cost of the selected drug per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection – or per volume or weight-based metric), weighted across dosage forms and strengths. This approach of negotiating a single price across all dosage forms and strengths aligns with the statutory requirement to negotiate an MFP for a selected drug. CMS believes this will also allow for a more direct comparison with the therapeutic alternative(s), which might have different

dosage forms, strengths, and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) than the selected drug.

Section 60.5 of this revised guidance describes the methodology CMS will use to translate the MFP once finalized (which, per above, will be an average price per 30-day equivalent supply for the selected drug) back into per unit (e.g., tablet) prices at the dosage form and strength level for the purposes of publishing per-unit MFPs for the different dosage forms and strengths of the selected drug at the NDC- 9 and NDC-11 levels, as contemplated under section 1196(a)(2). In addition to the description of that methodology included in this revised guidance, CMS will share the inputs behind that methodology specific to the selected drug with the Primary Manufacturer of the selected drug during the negotiation period such that the Primary Manufacturer will have visibility into the implied unit prices based on the MFP for each dosage form and strength throughout the negotiation process (i.e., any offer or counteroffer that identifies a single price would be clearly translatable to per unit prices at the dosage form and strength level). Please see section 60.5 of this revised guidance for details.

60.2 Limitations on Offer Amount

In accordance with section 1194(b)(2)(F)(i) of the Act, in negotiating the MFP of a selected drug, with respect to initial price applicability year 2026, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. This section 60.2 of this revised guidance provides details on the determination of the ceiling for the MFP and comparison of the ceiling to the MFP.

60.2.1 Determination of the Ceiling for the MFP

In accordance with section 1194(c) of the Act, for initial price applicability year 2026, the ceiling for the MFP for a selected drug shall not exceed the lower of the following:

- As described in section 60.2.2 of this revised guidance, an amount equal to the sum of the plan-specific enrollment weighted amounts; or
- As described in section 60.2.3 of this revised guidance, an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.[58]

CMS interprets the language in section 1194(c)(1)(A) of the Act to mean it should calculate a single amount across all dosage forms and strengths of the selected drug for the sum of the plan-specific enrollment weighted amounts and for the applicable percent of the average non-FAMP in order to determine which one is lower and will serve as the ceiling for the MFP. To determine whether the sum of the plan-specific enrollment weighted amounts or the applicable percent of the average non-FAMP will be used to calculate the ceiling for the MFP, CMS will aggregate the

[58] The September 2021 CPI-U, not seasonally unadjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.202 percent. Data retrieved from https://www.bls.gov/cpi/data.htm on May 16, 2023.

amounts determined for each NDC-11 for the selected drug to calculate a single amount – separately for each methodology – across dosage forms, strengths, and package sizes of the selected drug. These amounts can then be directly compared, and the ceiling for the single MFP of the selected drug (including all dosage forms and strengths) will be the lower amount.

CMS will calculate a single ceiling per 30-day equivalent supply (please see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology) across all dosage forms and strengths of the selected drug. Using the price per 30-day equivalent supply to calculate this amount facilitates aggregation across dosage forms and strengths of a selected drug where units (e.g., mg versus ml) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ. Sections 60.2.2 and 60.2.3 of this revised guidance describe the process for calculating the sum of the plan-specific enrollment weighted amounts and for calculating the applicable percent of the average non-FAMP, respectively, and section 60.2.4 describes the selection of the ceiling for the single MFP.

For new NDCs included in the definition of the selected drug that are marketed before the ceiling is calculated, the new NDC will be included in the ceiling calculation (as described in this section) provided that CMS receives non-FAMP price data for at least one calendar quarter in calendar year 2021 (or for the first full calendar year following market entry) and observes PDE days supply, PDE quantity dispensed, and PDE gross expenditures for at least one quarter in calendar year 2022, and DIR amounts for calendar year 2022.

CMS will not include a new NDC in the ceiling calculation if any of the above PDE elements do not have at least one calendar quarter of data in calendar year 2022 or if there are no DIR amounts for calendar year 2022 or the Primary Manufacturer did not submit non-FAMP price data for at least one quarter of calendar year 2021 (or for the first full calendar year following market entry).

60.2.2 Sum of the Plan-Specific Enrollment Weighted Amounts

In accordance with section 1194(c)(1)(B)(i) of the Act, CMS will calculate for a selected drug an amount equal to the sum of the plan-specific enrollment weighted amounts determined using the methodology described in section 1194(c)(2) of the Act. Plan sponsors report Part D PDE data to CMS at the NDC-11 level. Sponsors also report Direct and Indirect Remuneration (DIR) data to CMS at the NDC-11 level in the annual Detailed DIR Report. CMS will use these reported data for plan year 2022, which is the most recent year for which data will be available, for the purpose of determining the sum of the plan-specific enrollment weighted amounts for a selected drug for initial price applicability year 2026.

CMS will include all Part D plans that have PDE data for dosage forms and strengths of the selected drug in this calculation. Because CMS will have no PDE data for Part D plans in the following circumstances, such Part D plans will, by definition, be excluded from the calculation of the plan-specific enrollment weighted amounts: (1) plans that have no utilization for the selected drug and (2) plans that have no enrollment for 2022.[59] CMS will also exclude any PDE

[59] CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.

records for the selected drug for which the total gross covered prescription drug cost is equal to $0.

CMS will calculate the sum of the plan-specific enrollment weighted amounts in two stages. First, CMS will calculate the sum of the plan-specific enrollment weighted amounts for each NDC-9 associated with NDC-11s included on the list of NDC-11s of the selected drug in the CMS HPMS (see section 40.2 of this revised guidance). Second, CMS will calculate the sum of the plan-specific enrollment weighted amounts across these NDC-9s. The amounts calculated at each stage are for a 30-day equivalent supply (see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology).

To determine the sum of the plan-specific enrollment weighted amounts for each NDC-9 and across all NDC-9s of the selected drug, CMS will conduct the following steps.

Steps 1 through 8 will result in the sum of the plan-specific enrollment weighted amounts for each NDC-9 of the selected drug:

1. For each Part D plan, CMS will identify the PDE data for the selected drug for 2022 (that is, PDE records with dates of service during the period beginning on January 1, 2022 and ending on December 31, 2022).
2. For each Part D plan and each NDC-9, CMS will separately sum the negotiated price amounts (as defined in 42 C.F.R. § 423.100), the estimated rebate at point-of-sale amounts (ERPOSA), and units dispensed.
3. For each Part D plan and each NDC-9, CMS will sum the total DIR amounts found in the 2022 Detailed DIR Report and subtract the total ERPOSA calculated in step 2 to avoid double counting price concessions applied at the point of sale.
4. For each Part D plan and each NDC-9, CMS will subtract the total DIR minus ERPOSA amount calculated in step 3 from the total negotiated price amounts calculated in step 2 and then divide by the total units dispensed also determined in step 2. This calculation results in the NDC-9 price per unit, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan.
5. Separately, CMS will identify the total number of individuals enrolled in all Part D plans in December 2022 and the total number of individuals enrolled in each Part D plan in that same month.[60] The Part D plans included in both calculations of step 5 will be restricted to Part D plans with at least one PDE record for the selected drug in calendar year 2022.
6. For each Part D plan and each NDC-9, CMS will divide the total number of Part D beneficiaries enrolled in the Part D plan during December 2022 as identified in step 5 by the total number of individuals enrolled in all Part D plans in December 2022 also as identified in step 5, and multiply this quotient by the price per unit, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan, calculated in step 4, to arrive at the plan-specific enrollment weighted amount.
7. For each NDC-9, CMS will then sum the amounts calculated in step 6 across all Part D plans to calculate the sum of the plan-specific enrollment weighted amounts.

[60] CMS conducted an analysis of monthly Part D plan enrollment changes during 2022 and determined that monthly enrollment changes were the lowest from November to December, so CMS chose December as the most stable month to identify enrollment. The choice of one month to identify enrollment also allows the weights calculated in step 6 to sum to one.

8. For each NDC-9, CMS will then multiply the sum of the plan-specific enrollment weighted amounts calculated in step 7, which are a per unit price, by the NDC-9 average number of units per 30-day equivalent supply calculated from PDE data for 2022 to yield the price of a 30-day equivalent supply.

Steps 9 through 10 result in the sum of the plan-specific enrollment weighted amounts across all NDC-9s of the selected drug:

9. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s, both calculated from 2022 PDE data, and multiply this quotient by the sum of the plan-specific enrollment weighted amounts for a 30-day equivalent supply as calculated in step 8.
10. CMS will then sum amounts calculated in step 9 across all NDC-9s to generate the sum of the plan-specific enrollment weighted amounts for the selected drug for a 30-day equivalent supply.

60.2.3 Average Non-Federal Average Manufacturer Price

In accordance with section 1194(c)(1)(C)(i) of the Act, for initial price applicability year 2026, CMS will calculate an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, CMS will use the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) (CPI-U) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.[61]

For this calculation, CMS will use the non-FAMP price and unit volume data, as provided by the Primary Manufacturer, for each NDC-11 included on the list of NDC-11s of the selected drug in the CMS HPMS (see section 40.2 of this revised guidance), for each quarter of calendar year 2021 that is submitted to CMS by the Primary Manufacturer pursuant to section 1193(a)(4)(A) of the Act (as described in section 50.1 of this revised guidance) to calculate an annual average non-FAMP per unit. CMS will use 2022 PDE quantity dispensed and days supply data submitted to CMS at the NDC-11 level by Part D plan sponsors for the following: to calculate an annual average non-FAMP per unit for each NDC-9 of the selected drug, to calculate the annual average non-FAMP per 30-day equivalent supply for each NDC-9 of the selected drug, and to calculate the annual average non-FAMP per 30-day equivalent supply for the selected drug. In order to directly compare the amount calculated based on the applicable percent of average non-FAMP and the amount calculated based on the sum of the plan-specific enrollment weighted amounts (as described in section 60.2.2 above), CMS will base the average non-FAMP calculations on a 30-day equivalent supply and use the same 2022 PDE data for weighting both the sum of the plan-specific enrollment weighted amounts and the average non-FAMP across dosage forms and strengths to determine which amount is lower.

CMS will calculate the applicable percent of the average non-FAMP in two stages to determine the ceiling for the MFP. First, CMS will calculate the applicable percent of the average non-FAMP for each NDC-9 of the selected drug. Second, CMS will calculate the applicable percent

[61] The September 2021 CPI-U, not seasonally adjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.202 percent. Data retrieved from https://www.bls.gov/cpi/data.htm on May 16, 2023.

of the average non-FAMP across NDC-9s of the selected drug. The amounts calculated in each stage are for a 30-day equivalent supply (see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology).

To determine the applicable percent of the average non-FAMP for each NDC-9 and across all NDC-9s of the selected drug, CMS will conduct the following steps.

Steps 1 through 9 will result in the average non-FAMP, adjusted for inflation and with the applicable percent applied, for each NDC-9 of the selected drug:

1. To calculate an average non-FAMP that is comparable to the sum of the plan-specific enrollment weighted amounts described in section 60.2.2 of this revised guidance, CMS will compare the non-FAMP unit type (e.g., tablet) to the PDE units (i.e., each, milliliter, and grams). In instances where the units are different, CMS will convert the non-FAMP unit type to the PDE units so that the two amounts (average non-FAMP and sum of the plan-specific enrollment weighted amounts) represent the same quantity of the selected drug.[62]
2. For each NDC-11 and for each quarter during calendar year 2021, CMS will calculate the non-FAMP per unit by dividing the non-FAMP per package by the total number of units per package.
    - Note: If the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 50.1.1 of this revised guidance), CMS will use the non-FAMP for the quarters of the first full calendar year following the market entry for such drug.
3. For each NDC-11 and for each quarter during calendar year 2021, CMS will divide the total unit volume (calculated as the product of the total number of packages sold by the number of units per package from manufacturer-reported non-FAMP data) in that quarter by the total unit volume across all four quarters during calendar year 2021 (also from manufacturer reported non-FAMP data), and multiply this quotient by the non-FAMP per unit calculated in step 2.
    - Note: If the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 50.1.1 of this revised guidance), CMS will use the non-FAMP and total unit volumes for the quarters of the first full calendar year following the market entry for such drug.
4. For each NDC-11, CMS will sum the amounts calculated in step 3 across quarters to calculate the average non-FAMP per unit for that NDC-11 for the calendar year CMS believes steps 3 and 4 are necessary to account for non-FAMP unit volume fluctuations that may occur across quarters.
5. For each NDC-11, CMS will divide the total quantity dispensed for that NDC-11 by the total quantity dispensed for all applicable NDC-11s of the same NDC-9 (both calculated from 2022 PDE data) and multiply this quotient by the average non-FAMP per unit for the calendar year calculated in step 4.
6. For each NDC-9, CMS will sum the amounts calculated in step 5 to calculate the average non-FAMP per unit for that NDC-9 for the calendar year. CMS believes steps 5 and 6 are

[62] PDE units are industry standard National Council for Prescription Drug (NCPDP) defined values of each, milliliter, and grams. See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

necessary to account for fluctuations in quantity dispensed that may occur across NDC-11s of an NDC-9 in the Medicare Part D population.

7. For each NDC-9, CMS will then increase the average non-FAMP per unit for calendar year 2021 calculated in step 6 by the percentage increase in CPI-U (all items; United States city average) from September 2021 until September 2022 as specified in section 1194(c)(1)(C)(i) of the Act.
    - Note: For initial price applicability year 2026, if the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021(as described in section 50.1.1 of this revised guidance), and the non-FAMP is based on data from the first full calendar year following the market entry of the such drug, which can only be calendar year 2022, CMS will not apply the CPI-U adjustment.
8. For each NDC-9, after CMS has calculated the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable, CMS will then apply the applicable percent specified in section 1194(c)(3) of the Act for the monopoly type determined for the selected drug based on its initial approval date (described in section 30.1 of this revised guidance). Applying the applicable percent here, in step 8, results in the same step 11 amount as would result if CMS were to apply the applicable percent to the average non-FAMP per 30-day equivalent supply for the selected drug in step 11. The definition of each monopoly type and the applicable percentage are described below for initial price applicability year 2026. CMS notes that the "extended-monopoly" type is not discussed below because the definition of extended-monopoly drug under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030. CMS interprets this to mean that no selected drug will be considered an extended-monopoly drug for purposes of calculating the ceiling prior to initial price applicability year 2030.

Figure 2: Monopoly Types and Applicable Percentage for Initial Price Applicability Year 2026

Monopoly Type	Definition	Applicable Percentage	Note
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act)[63]	For initial price applicability year 2026, a selected drug that is not a long-monopoly drug or a selected drug that is a vaccine licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	75%	The first approval date, under section 505(c) of the FD&C Act, associated with the initial FDA application number for the active moiety (or fixed combination drug) must be after January 1, 2010 and before September 1, 2016. The first licensure date, under section 351(a) of the PHS Act, associated with the initial FDA application number for the active ingredient (or fixed combination drug) must be after January 1, 2010 and before September 1, 2012.
Long-monopoly drug (section 1194(c)(5)(A) of the Act)	A selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term 'long-monopoly drug' does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	40%	The first approval date under section 505(c) of the FD&C Act or the first licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or fixed combination drug) must be on or before January 1, 2010.

9. For each NDC-9, CMS will then multiply the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied as calculated in step 8 by the quotient of the total quantity dispensed divided by the total 30-day equivalent supply (i.e., this quotient represents the average units per 30-day supply equivalent for that NDC-9) calculated from 2022 PDE data to determine the

[63] Because the definition of extended-monopoly drug at section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with CMS with respect to an initial price applicability year before 2030, for initial price applicability year 2026, any drug, biological product, or vaccine that is not considered a long-monopoly drug will be considered a short monopoly drug.

average non-FAMP for a 30-day equivalent supply. As described above in section 60.2.1 of this revised guidance, CMS believes calculating the average non-FAMP for a 30-day equivalent supply is necessary to account for different units and treatment regimens across dosage forms and strengths.

Steps 10 and 11 will calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with applicable percent applied, across all NDC-9s of the selected drug:

10. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s of the selected drug, both calculated from 2022 PDE data, and multiply this quotient by the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied, calculated in step 9.
11. CMS will then sum amounts calculated in step 10 across all NDC-9s of the selected drug to calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied, for the selected drug.

60.2.4 Selection and Application of the Ceiling for the MFP

CMS will compare the values calculated in step 10 of section 60.2.2 of this revised guidance (sum of the plan-specific enrollment weighted amounts) and step 11 of section 60.2.3 of this revised guidance (applicable percent of the average non-FAMP) and select the lower value as the ceiling for the selected drug. Once CMS has identified whether the ceiling would be determined by the sum of the plan-specific enrollment weighted amounts or the applicable percent of the average non-FAMP, CMS will ensure that the MFP per 30-day equivalent supply, as negotiated through the process described in sections 60.3 and 60.4 of this revised guidance, is no greater than the lower ceiling.

60.3 Methodology for Developing an Initial Offer

Section 1194(e) of the Act directs CMS to consider certain factors related to manufacturer-specific data and available evidence about therapeutic alternative(s) as the basis for determining offers and counteroffers in the negotiation process. The statute requires CMS to provide the manufacturer of a selected drug with an initial offer and a concise justification based on the factors described in section 1194(e) that were used in developing the offer; however, CMS has the discretion to determine how and to what degree each factor should be considered.

As discussed in greater detail below, consistent with section 1194(e) of the Act, for the purposes of determining an initial offer, CMS will (1) identify therapeutic alternative(s), if any, for the selected drug as described in section 60.3.1 of this revised guidance; (2) use the Part D net price for the therapeutic alternative(s) that is covered under Part D and/or the Average Sales Price (ASP) for the therapeutic alternative(s) that is covered under Part B to determine a starting point for developing an initial offer as described in section 60.3.2 of this revised guidance; (3) evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)) for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2) of the Act, including whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations, as described in section 60.3.3 of this revised

guidance (resulting in the "preliminary price"); and (4) further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act (described in section 60.3.4 of this revised guidance) to determine the initial offer price.

Pursuant to section 1194(b)(2)(F) of the Act, CMS will not make any offers or accept any counteroffers for the MFP that are above the statutorily defined ceiling.

60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication

For initial price applicability year 2026, CMS will identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act for a selected drug, using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. CMS will consider off-label use when identifying indications if such use is included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia.[64]

For each indication of the selected drug, CMS will next identify a pharmaceutical therapeutic alternative(s). CMS considered evaluating non-pharmaceutical therapeutic alternatives; however, for initial price applicability year 2026, CMS will only consider therapeutic alternatives that are drugs or biologics covered under Part D or Part B. CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials. For purposes of this revised guidance, the term "therapeutic alternative" may refer to one or more therapeutic alternative(s) or a subset of the most clinically comparable therapeutic alternatives.

To identify potential therapeutic alternatives for the indications of a selected drug, CMS will use data submitted by the Primary Manufacturer and the public, FDA-approved indications, drug classification systems commonly used in the public and commercial sector for formulary development, indications included in CMS-approved Part D compendia, widely accepted clinical guidelines, the CMS-led literature review, drug or drug class reviews, and peer-reviewed studies. In addition to brand name drugs and biologics, CMS will consider generic drugs and biosimilars when identifying a therapeutic alternative(s) to a selected drug. CMS will consider off-label use for therapeutic alternatives when identifying indications if such use is included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia.

CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on the subset of therapeutic alternatives that are most clinically comparable to the selected drug for the purpose of developing the initial offer. CMS may consult with FDA to obtain information regarding other approved therapies for the same indication and may also consult with clinicians, patients or patient organizations, and/or academic experts, to ensure that appropriate therapeutic alternatives are identified. If a therapeutic alternative has not yet been incorporated into nationally recognized, evidence-based guidelines, CMS will consider clinical evidence available

[64] CMS-approved Part D compendia are described in Chapter 6, § 10.6 of the Prescription Drug Benefit Manual.

through a literature search and information submitted by the Primary Manufacturer and the public to inform the selection of a therapeutic alternative(s). In all cases, CMS will select therapeutic alternatives based on clinical appropriateness.

60.3.2 Developing a Starting Point for the Initial Offer

CMS considered several options for what price should be used as the starting point for developing the initial offer. Options considered included the use of the Part D net price(s) and/or the ASP(s) of therapeutic alternative(s), if any, to the selected drug, the unit cost of production and distribution for the selected drug, the ceiling for the selected drug (as described in section 60.2 of this revised guidance), a domestic reference price for the selected drug (e.g., the Federal Supply Schedule[65] (FSS) price), or a "fair profit" price for the selected drug based on whether R&D costs have been recouped and margin on unit cost of production and distribution. Under any of these options, the initial offer and final MFP would be capped at the statutory ceiling.

After considering these options and in accordance with section 1194(e)(2)(A) of the Act which directs CMS to consider the cost of therapeutic alternative(s), CMS will use the Part D net price(s) ("net price(s)") and/or ASP(s) of the therapeutic alternative(s) (or a subset of the most clinically comparable therapeutic alternatives) for the selected drug, as applicable, as the starting point for developing the initial offer unless this net price or ASP is greater than the statutory ceiling (described in section 60.2 of this revised guidance), and will then consider adjustments based on section 1194(e)(2) data and manufacturer-submitted data per section 1194(e)(1). CMS intends to identify the price of each therapeutic alternative that is covered under Part D net of all price concessions received by any Part D plan or pharmacy benefit manager on behalf of the Part D plan by using PDE data and detailed DIR report data. In taking this approach, CMS acknowledges that the therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit, however, using net prices and ASPs of therapeutic alternatives enables CMS to start developing the initial offer within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition. By using the price(s) of the selected drug's therapeutic alternative(s), CMS will be able to focus the initial offer on clinical benefit by adjusting this starting point relative to whether the selected drug offers more, less, or similar clinical benefit compared to its therapeutic alternative(s). The other options considered do not provide a starting point that reflects the cost of therapeutic alternatives in the current market, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries relative to the other drug(s) available to treat the patient's disease or condition.

When comparing prices of therapeutic alternatives for purposes of informing a starting point for the initial offer, CMS may use an alternative methodology for calculating a 30-day equivalent supply as appropriate. For example, because Part B claims data do not contain a "days' supply" field similar to PDE data, CMS may use an alternative methodology to calculate the price per 30-day equivalent supply for therapeutic alternatives covered under Part B.

[65] The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsa-schedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20government.

If there is one therapeutic alternative for the selected drug, CMS will use the net price or ASP, as applicable, of the therapeutic alternative (if it is lower than the ceiling) as the starting point to develop CMS' initial offer for the MFP. If there are multiple therapeutic alternatives, CMS will consider the range of net prices and/or ASPs, including the prices of generic and biosimilar therapeutic alternatives, as well as the utilization of each therapeutic alternative relative to the selected drug, to determine the starting point within that range. If the selected drug has no therapeutic alternative, if the prices of the therapeutic alternatives identified are above the statutory ceiling for the MFP (as described in section 60.2 of this revised guidance), or if there is a single therapeutic alternative with a price above the statutory ceiling for the MFP, then CMS will determine the starting point for the initial offer based on the FSS or "Big Four Agency"[66] price ("Big Four price"). If the FSS and Big Four prices are above the statutory ceiling, then CMS will use the statutory ceiling as the starting point for the initial offer. In all cases, this starting point will be subject to adjustments as described further below.

60.3.3 Adjusting the Starting Point Based on Clinical Benefit

To evaluate the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), as applicable, CMS will broadly evaluate the body of clinical evidence, including data received from the public and manufacturers as described in section 50.2 of this revised guidance, and data identified through a CMS-led literature review. CMS may also analyze Medicare claims or other datasets for utilization patterns of the selected drug versus its therapeutic alternative(s), clinical data, or other information relevant to the selected drug and its therapeutic alternative(s) and may consult with clinicians, patients or patient organizations, academic experts, and/or the FDA. As described in section 60.4 of this revised guidance, CMS will provide additional engagement opportunities for interested parties—specifically, meetings with manufacturers and patient-focused listening sessions—after the October 2, 2023 deadline for submission of section 1194(e)(2) data (further described in section 60.4 of this revised guidance).

This approach provides a pathway for CMS to consider the multitude of information expected from public input, including but not limited to peer-reviewed research, expert reports or whitepapers, clinician expertise, real-world evidence, and patient experience. This approach also provides flexibility for CMS to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

Once the starting point for the initial offer has been established and evidence on clinical benefit has been considered, CMS will adjust the starting point for the initial offer based on the review of the clinical benefit. CMS will not, per section 1194(e)(2) of the Act, use evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual

[66] The Big Four price is the maximum price a drug manufacturer is allowed to charge the "Big Four" federal agencies, which are the Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard. See section 8126 of title 38 of the U.S. Code. See: https://www.cbo.gov/publication/57007.

who is younger, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs. CMS considered employing both a qualitative approach (e.g., adjusting the starting point upward or downward relative to the clinical benefit offered by the selected drug compared to its therapeutic alternatives) and a more thoroughly pre-specified quantitative approach. CMS will use a qualitative approach to preserve flexibility in negotiation, including the ability to consider nuanced differences between different drugs, for example interactions with other treatments commonly prescribed simultaneously for a condition or disease, and other factors that might not be captured in a more thoroughly pre-specified quantitative approach.

60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

To consider comparative effectiveness between a selected drug and its therapeutic alternative(s), CMS will identify outcomes to evaluate for each indication of the selected drug. CMS will consider the identified outcomes, including patient-centered outcomes[67] and patient experience data, when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s). When reviewing such information, as noted above, CMS will not, per section 1194(e)(2), use evidence in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs. Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients and patient-reported outcomes will also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug, including patient-centered outcomes when available. CMS may also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug. Relevant outcomes will be identified using the CMS-led literature review and information submitted by manufacturers and the public, including patients and caregivers, through the Negotiation Data Elements ICR described in section 50 of this revised guidance, as well as in the patient-focused listening sessions described in section 60.4.

In all cases, CMS will consider applicable evidence and other input collectively, within the context of the course of care for the condition(s) or disease(s) that the selected drug is indicated to treat, and in accordance with section 50 of this revised guidance. As noted previously, this approach provides flexibility to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

[67] A patient-centered outcome is defined as: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves. (Source: ISPOR Plenary, Patrick (2013) via FDA's *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders*, June 2020.) See: https://www.fda.gov/media/139088/download.

CMS will also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations as required by section 1194(e)(2)(C) of the Act. In doing so, CMS will evaluate access, equity, and health outcomes for specific populations. To do so, CMS will seek to identify studies focused on the impact of the selected drug and its therapeutic alternative(s) on individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries. Specific populations may include underserved and underrepresented populations, as applicable. Further, CMS will consider whether the selected drug fills an unmet medical need, which CMS will define as treating a disease or condition in cases where no other treatment options exist or existing treatments do not adequately address the disease or condition. CMS will consider each selected drug and its therapeutic alternatives to determine whether the drug fills an unmet medical need at the indication level as of the time the section 1194(e)(2) data is submitted. CMS will consider the nonbinding recommendations in the FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics,"[68] as well as any updates that may be issued by FDA in the future, when determining if a selected drug addresses an unmet medical need.

CMS will determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression). CMS understands that a selected drug can be first in class,[69] however, other drugs may have become available since the selected drug's initial approval. In accordance with section 1194(e)(2)(A) of the Act, CMS will review the analyses detailed above for each indication for the selected drug and its therapeutic alternative(s) and determine, based on the relevant information and evidence, what the difference in clinical benefit is between the selected drug and the therapeutic alternative(s).

As previously noted, CMS will take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug and its therapeutic alternative(s) as well as the patient population(s) taking the selected drug. For each selected drug, the applicable starting point will first be adjusted (i.e., apply an upward or downward adjustment, or no adjustment) based on the totality of the relevant information and evidence submitted and gathered through CMS' analysis based on the clinical benefit the selected drug provides (and then subsequently it will be adjusted by the manufacturer-submitted data described in section 60.3.4). Because the extent of clinical benefit may vary across different indications, CMS may adjust the starting point based on the clinical benefit for an individual indication in cases where the clinical benefit of the selected drug is notably different than the therapeutic alternative(s) for that specific indication.

60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives

Similar to a selected drug with at least one therapeutic alternative, the starting point for a selected drug without a therapeutic alternative will be adjusted based on the totality of relevant information and evidence as detailed above, such as outcomes and impact on specific

[68] FDA Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics, May 2014. See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics.

[69] First in class drugs are those that have a new mechanism of action, defined by the National Cancer Institute as "a term used to describe how a drug or other substance produces an effect in the body." See: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action.

populations, submitted through the Negotiation Data Elements ICR and gathered through CMS' analysis of the clinical benefit the selected drug provides.

CMS will consider whether the selected drug fills an unmet medical need separately for each indication. A selected drug will be considered to meet an unmet medical need for an indication included in the analysis when it is used to treat a disease or condition where no other treatment options exist or existing treatments do not adequately address the disease or condition. As noted previously, CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics," as well as any updates that may be issued by FDA in the future, when considering if a drug addresses an unmet medical need for the purpose of the Negotiation Program. A selected drug may be considered a therapeutic advance when a substantial improvement in outcomes is observed for an indication.

60.3.3.3 Preliminary Price

After the starting point has been adjusted, as appropriate, based on section 1194(e)(2) data submitted by manufacturers and the public through the Negotiation Data Elements ICR and gathered through CMS-led analyses and literature review, the resulting price is referred to as "the preliminary price." As described in section 60.3.4 of this revised guidance, the preliminary price will be adjusted, as appropriate, based on data submitted by the Primary Manufacturer in accordance with section 1194(e)(1) of the Act.

60.3.4 Adjusting the Preliminary Price Based on Consideration of Manufacturer-Specific Data

Under section 1194(e)(1) of the Act, CMS must also consider data reported by the Primary Manufacturer, as described in section 50.1 of this revised guidance. The adjustment to the preliminary price applied on the basis of these data, if any, may be upward or downward, as needed to account for these manufacturer-specific data elements. These data elements are: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug; and (5) market data and revenue and sales volume data for the drug in the United States.

CMS will consider the five elements outlined in section 1194(e)(1) of the Act in totality and apply an upward adjustment, downward adjustment, or no adjustment to the preliminary price. To do this, CMS may consider each factor in isolation or in combination with other factors. CMS provides illustrative examples for the manufacturer-specific data elements below. However, the overall adjustment, inclusive of all five elements taken together, may differ from the example adjustment for any single element viewed in isolation.

In considering element (1) above on R&D costs, CMS will consider the extent to which the Primary Manufacturer has recouped its R&D costs. CMS will compare the R&D costs with the global and U.S. total lifetime net revenue for the selected drug reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its R&D costs. For example, if a Primary Manufacturer has not recouped its R&D costs, CMS may

consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its R&D costs, CMS may consider adjusting the preliminary price downward or apply no adjustment. CMS may use the R&D costs reported by the Primary Manufacturer and the calculated recouped costs, including the assumptions and calculations in the accompanying narrative text, and/or other factors as described in the Negotiation Data Elements ICR and in Appendix C of this revised guidance to adjust the preliminary price.

In considering element (2) on current unit costs of production and distribution, CMS will consider the relationship between the preliminary price and the unit costs of production and distribution. For example, CMS may consider adjusting the preliminary price downward if the unit costs of production and distribution are lower than the preliminary price, or upward if the unit costs of production and distribution are greater than the preliminary price. Again, CMS may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug to determine if an adjustment is appropriate.

In considering element (3) on prior Federal financial support, CMS will consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

In considering element (4) on patent applications, exclusivities, and applications and approvals for the selected drug, CMS will review the patents and exclusivities reported as it develops its initial offer. CMS believes that this information will support CMS' consideration of the 1194(e)(1) and 1194(e)(2) factors described in section 50 of this revised guidance. For instance, patents and exclusivities may inform CMS' understanding of therapeutic alternatives and other available therapy for the purposes of adjusting for clinical benefit, including consideration of whether the selected drug represents a therapeutic advance or meets an unmet medical need. More specifically, in light of exclusivities, there may be no other available therapy aside from the selected drug that adequately addresses treatment or diagnosis of a disease or condition, and consideration of such information would be relevant to CMS' consideration of the extent to which the selected drug addresses an unmet medical need for that disease or condition.

Finally, in considering element (5) on market data and revenue and sales volume data for the U.S., CMS will consider how the data compare to the CMS preliminary price. For example, if the average commercial net price is lower than the preliminary price, CMS may consider adjusting the preliminary price downward. If the average commercial net price is greater than the preliminary price, CMS may consider adjusting the preliminary price upward.

Appendix C of this revised guidance includes a list of definitions that CMS adopts for the purposes of describing the data to be collected with respect to the data elements listed in section 1194(e)(1) of the Act.

After any adjustments to the preliminary price are made under this section 60.3.4 of this revised guidance, the result is the initial offer.

60.4 Negotiation Process

In accordance with sections 1191(b)(4)(A) and 1191(d)(2)(A) of the Act, and as described in section 40.1 of this revised guidance, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into an Agreement, or, for initial price applicability year 2026, October 1, 2023. CMS will implement the negotiation process consistent with the requirements of the statute, with the aim of achieving "the lowest maximum fair price for each selected drug" consistent with section 1194(b)(1) of the Act.

After the submission of the section 1194(e) data by manufacturers and other interested parties by October 2, 2023, CMS will host meetings with Primary Manufacturers of selected drugs that have submitted section 1194(e) data and other interested parties. CMS will invite the Primary Manufacturer for each selected drug to one meeting in Fall 2023 after the data submission deadline. The purpose of this meeting will be for the Primary Manufacturer to provide additional context on its data submission and share new section 1194(e)(2) data, if applicable, as CMS begins reviewing the data and developing an initial offer. Primary Manufacturers may bring materials to facilitate discussion and CMS may request any materials presented afterwards. Primary Manufacturers are limited to sharing 50 pages (or a combination of pages, slides, and/or charts and graphs totaling 50 pages) of material, in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting, anticipating that these materials may contain cross-references to other material, particularly other material already submitted to CMS. CMS will also host patient-focused listening sessions with interested parties. These meetings are intended to bring together patients, beneficiaries, caregivers, and consumer and patient organizations as well as other interested parties to share patient-focused feedback with CMS on therapeutic alternatives and other information as CMS reviews section 1194(e)(2) data submissions and develops an initial offer for each selected drug. More information about these listening sessions will be forthcoming.

CMS acknowledges that Primary Manufacturers may benefit from having access to the section 1194(e)(2) data submitted by other interested parties during the negotiation period. In addition to offering the meetings above, CMS will aim to share redacted section 1194(e)(2) data with the Primary Manufacturer of a selected drug during the negotiation process when feasible. The data will be redacted as per the confidentiality standards described in section 40.2 of this revised guidance and will not include proprietary information, PHI / PII, or information that is protected from disclosure under other applicable law.

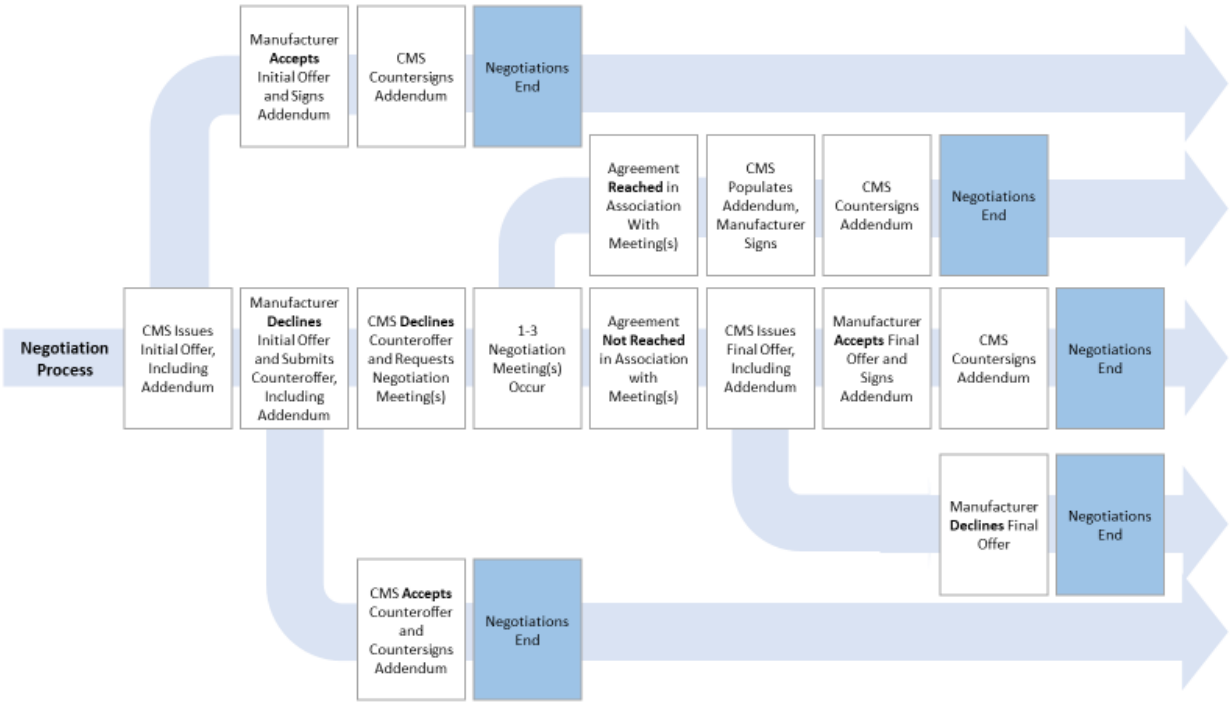
In accordance with sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug for initial price applicability year 2026 no later than February 1, 2024. This written initial offer will be accompanied by an Addendum to the Agreement populated with the proposal for the MFP, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP if such agreement is reached at this stage.

After the written initial offer from CMS is sent to the Primary Manufacturer, the negotiation process may include the following steps, depending on when and whether agreement on the MFP is reached and an offer is accepted:

(1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer, including an Addendum populated with the counteroffer MFP as described in section 60.4.2 of this revised guidance, from the Primary Manufacturer (if CMS' written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer from CMS;
(2) in accordance with section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written manufacturer counteroffer, which CMS will provide within 30 days;
(3) if the Primary Manufacturer's written counteroffer is not accepted by CMS, up to three possible in-person or virtual negotiation meetings between the Primary Manufacturer and CMS; and
(4) a final written offer, including an Addendum containing the final offer MFP as described in section 60.4.4 of this revised guidance, made by CMS to the Primary Manufacturer, if no agreement is reached before the end of the negotiation meetings.

Every offer and counteroffer will include an Addendum populated with the offered/counteroffered MFP. If an agreement is reached at any point during the negotiation process by the Primary Manufacturer accepting CMS' written initial offer or final offer (as described in section 60.4.4 of this revised guidance), CMS accepting the Primary Manufacturer's counteroffer, or an agreement being reached in association with the negotiation meetings, the Addendum to the Agreement, as described in section 40.3 of this revised guidance, will be executed by both parties and will constitute agreement on the MFP. Section 60.4.4 of this revised guidance describes how and when the Addendum will be created and signed. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2026 and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable. The diagram below provides a non-exhaustive list of possible paths the negotiation process could take after CMS' initial offer, for a process taking place within the statutorily specified timelines.

Figure 3. Possible Negotiation Paths



During the entire negotiation process, CMS cannot offer or agree to any manufacturer counteroffer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and as described in section 60.2 of this revised guidance.

If the Primary Manufacturer is delayed in meeting one or more deadlines related to establishing the Agreement, submitting required data, and/or submitting the counteroffer, CMS will continue to engage in the negotiation process and will take the time to complete the established process as described in this section. During the period of time from when the Primary Manufacturer fails to meet a deadline until the date the Primary Manufacturer comes into compliance with the negotiation process, CMS will consider the Primary Manufacturer in violation of the Agreement and the Primary Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act. Section 90.3 and section 100 of this revised guidance further address possible actions to address noncompliance.

60.4.1 Provision of an Initial Offer and Justification

In accordance with section 1194(b)(2)(B) of the Act, the written initial offer from CMS, provided no later than February 1, 2024, must include a concise justification for the offer based on the data described in section 50 of this revised guidance. The justification will include a qualitative description of the factors from section 1194(e) (further described in sections 50 and 60.3 of this revised guidance) and a description of the methodology that CMS used to determine the initial offer. The information contained in the concise justification will provide the Primary Manufacturer with information on the range of evidence and other information considered pursuant to section 1194(e) that CMS found compelling during the development of the initial offer, thereby providing the Primary Manufacturer the necessary information to build a counteroffer if the Primary Manufacturer decides to reject the initial offer. The initial offer and

justification will not include information that CMS determines to be third-party proprietary pricing information, information that could lead to the calculation of a third party's proprietary information, PHI / PII, other information that is protected from disclosure under other applicable law, or the starting point.

No offer can exceed the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section 60.2 of this revised guidance. As feasible, CMS will provide information on the calculation of the statutorily-determined ceiling and the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer within 60 days of the Primary Manufacturer's submission of data that complies with the requirements described in section 50.1 of this revised guidance. As described in section 40.2.3 of this revised guidance, CMS may reach out to the Primary Manufacturer for clarity on its data submission if CMS determines the information is not complete or accurate. In situations when additional outreach to the Primary Manufacturer is required to clarify the submitted data, CMS will aim to provide information on the calculation of the statutorily-determined ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer as close to 60 days from the initial data submission as feasible. As described in section 40.5 of this revised guidance, a Primary Manufacturer will have 30 days to submit a suggestion of error regarding the calculation of the ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths for CMS' consideration.

60.4.2 Required Components of a Counteroffer

In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will have no more than 30 days from receipt of the written initial offer from CMS to respond in writing by either accepting the initial offer for the selected drug or making a written counteroffer and providing a justification for such counteroffer based on the data described in section 50 of this revised guidance. Any counteroffer should also respond to the justification provided in CMS' written initial offer. The Primary Manufacturer's response should focus on the elements described in section 1194(e) and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the data in section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS. Primary Manufacturers may also include in their counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) that supports the counteroffer MFP.

The Primary Manufacturer should provide a suggested MFP for the selected drug in its written counteroffer. As described in section 60.1 of this revised guidance, the counteroffer MFP should be made consistent with the manner that CMS' written initial offer was made; that is, a single price for the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. In accordance with section 1194(b)(2)(F) of the Act, CMS cannot accept a written counteroffer from a manufacturer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section 60.2 of this revised guidance.

On April 18, 2023, CMS published the Drug Price Negotiation Process ICR for 60-day comment to capture information related to the counteroffer that Primary Manufacturers may submit after receiving CMS' initial offer.[70] The Drug Price Negotiation Process ICR includes instructions and a form for Primary Manufacturers to submit written counteroffers in the case where CMS' written initial offer of an MFP for a selected drug is not accepted. The comment period for the Drug Price Negotiation Process ICR closed on June 20, 2023. There will be an additional opportunity to submit comments for 30 days after revisions and re-publication in the Federal Register.

In order for a written counteroffer to be considered complete, a Primary Manufacturer must complete an Addendum in the CMS HPMS in addition to responding to the Drug Price Negotiation Process ICR, as described in section 40.3 of this revised guidance. A completed Addendum would include, but is not limited to, the MFP the Primary Manufacturer is counteroffering and a signature by an authorized representative.

60.4.3 Negotiation Process After Manufacturer Counteroffer

In accordance with section 1194(b)(2)(D) of the Act, CMS will respond in writing to a written counteroffer made by the Primary Manufacturer. Although the statute does not specify a timeframe for CMS' response to the counteroffer, negotiations for initial price applicability year 2026 must end prior to August 1, 2024, i.e., an agreement on MFP for the selected drug must be reached no later than July 31, 2024, to avoid potential excise tax liability under 26 U.S.C. § 5000D(b)(2).

In the case CMS' written initial offer is not accepted, and the Primary Manufacturer submits a written counteroffer, CMS will consider the counteroffer and either accept or reject it in writing within 30 days of receipt of the counteroffer. When considering a counteroffer, CMS will evaluate whether accepting the counteroffer is consistent with the statutory directive to aim to arrive at an agreement that achieves the lowest possible MFP for the selected drug. If CMS' written response to the counteroffer rejects the Primary Manufacturer's written counteroffer, CMS will extend an invitation to the Primary Manufacturer for a negotiation meeting. CMS will offer to hold a minimum of one meeting between CMS and the Primary Manufacturer to discuss CMS' written initial offer, the Primary Manufacturer's written counteroffer, and data considered. After this initial meeting, CMS will give each party (CMS and the Primary Manufacturer) the opportunity to request one additional meeting, resulting in a maximum of three meetings between CMS and the Primary Manufacturer.

The scope for these negotiation meetings will focus on the section 1194(e) data, including the therapeutic alternative(s) for the selected drug, and how they should inform the MFP. During these negotiation meetings, discussion of disputes and program policies regarding the negotiation process will be considered out of scope. CMS and the Primary Manufacturer will each be permitted to bring up to six meeting attendees, and both parties must share its participant lists ahead of each meeting. CMS arrived at this meeting attendee number after considering the roles from each party that would be critical to the conversation while ensuring that the meeting is sized appropriately to encourage active discussion. Additionally, a maximum of six attendees per side

[70] Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). See: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.

is in line with requirements for similar meetings between government entities and manufacturers. Each meeting will last no more than two hours and may be conducted in-person at CMS or HHS headquarters. CMS believes two hours per negotiation meeting (of which there can be up to three meetings) is sufficient for a fruitful discussion and is appropriate considering time and scheduling constraints. If necessary, due to distance or scheduling challenges, meetings may be held virtually, or may be a "hybrid" arrangement where a portion of attendees are in-person and a portion of attendees are virtual. CMS' notes from negotiation meetings will be retained as part of the meeting record in compliance with applicable federal law including the Federal Managers Financial Integrity Act and the Federal Records Act and will be subject to the confidentiality policy described in section 40.2.1 of this revised guidance. Attendees on behalf of the Primary Manufacturer may take and keep notes of the meetings. Audio and/or video recording of negotiation meetings will not be permitted.

Correspondence regarding negotiation meetings will be conducted over email using the IRARebateandNegotiation@cms.hhs.gov mailbox. CMS will share a meeting agenda with the Primary Manufacturer via email approximately two weeks before the meeting. The Primary Manufacturer may request additions or edits to the agenda as long as they are in scope, as discussed in the paragraph above. Such requests must be submitted via email at least one week ahead of the meeting. CMS will circulate a final agenda two business days prior to the negotiation meeting. If a Primary Manufacturer would like to share materials at a negotiation meeting, such materials should be limited to 20 pages (or a combination of pages, slides, and/or charts and graphs totaling 20 pages), in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting, anticipating that these materials may contain cross-references to other material, particularly other material already submitted to CMS. Such materials must be submitted via email at least one week ahead of the meeting. Substantive discussion via email will not be permitted, in order for all attendees to benefit from such discussions as part of the negotiation meetings.

The meetings for initial price applicability year 2026 will occur between the time the Primary Manufacturer's written counteroffer is not accepted by CMS, which at the latest will be 30 days after the counteroffer is received, if applicable, and June 28, 2024. There would be about three months' time between CMS' rejection of the Primary Manufacturer's written counteroffer (approximately April 1, 2024) and the deadline for negotiation meetings to conclude (June 28, 2024). CMS requires that all negotiation meetings end no later than June 28, 2024, the last business day that is fifteen days prior to July 15, 2024, to allow CMS sufficient time to prepare a final offer (if an MFP was not reached in association with the negotiation meetings), send that final offer to the Primary Manufacturer by July 15, and to allow the Primary Manufacturer time to consider the final offer and accept or reject the final offer by July 31, 2024, as all negotiations must be concluded prior to August 1, 2024. These dates assume that a Primary Manufacturer is timely in entering into an Agreement, submitting information, and meeting deadlines related to the Negotiation Program.

CMS believes that the negotiation meeting process described above allows for a more efficient and effective approach than preparing and exchanging additional written offers and counteroffers. Negotiation meetings will also allow both parties to discuss any new information consistent with the data described in section 1194(e)(2) of the Act that may have become

available about the selected drug or its therapeutic alternative(s), and that may affect the determination of the MFP. Negotiation meetings will be attended solely by representatives of the Primary Manufacturer and of CMS. A written record will be developed and retained by CMS in compliance with applicable federal laws. The Primary Manufacturer can also develop and retain its own written record. As described in section 40.2.2 of this revised guidance, CMS will not publicly discuss ongoing negotiations with a Primary Manufacturer, including details of the negotiation meetings. Primary Manufacturers may publicly disclose information regarding ongoing negotiations with CMS at its discretion. If a Primary Manufacturer discloses information that is made public regarding any aspects of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer.

As described in section 60.6.1 of this revised guidance, in this public explanation, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, the exchange of offers and counteroffers, and the negotiation meetings while abiding by the confidentiality policy described in section 40.2 of this revised guidance.

When developing this negotiation process, CMS considered using solely a written offer and counteroffer approach. That is, CMS considered providing one written offer and allowing a Primary Manufacturer to make a single written counteroffer, as described in the statute. CMS also contemplated allowing each party to make up to two written offers or counteroffers (i.e., CMS makes an initial offer, Primary Manufacturer possibly makes a counteroffer, CMS possibly makes a second offer, Primary Manufacturer possibly makes a second counteroffer). However, CMS believes that an offer/counteroffer process that includes in-person or virtual meetings (or a hybrid approach) will most effectively facilitate the negotiation process to arrive at an MFP and is more consistent with current industry practices for drug price negotiation.

60.4.4 Determination that Negotiations Have Finished

In accordance with sections 1194(b)(2)(E) and 1191(d)(2)(B) of the Act, all negotiations between CMS and the manufacturer of the selected drug must end prior to August 1, 2024, for initial price applicability year 2026 to avoid potential excise tax liability.

In the event that negotiation meetings occurred and an MFP was not agreed to in association with the negotiation meetings, CMS will send the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" and an Addendum with the final offer MFP by July 15, 2024. This will serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. This final offer will only be sent if, by July 15, 2024, neither CMS nor the Primary Manufacturer has accepted the latest offer or counteroffer made in writing or agreed upon an MFP in association with the negotiation meetings. If a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by July 31, 2024. The following table details CMS' timing for the negotiation process for initial price applicability year 2026:

Date[71]	**Milestone**
February 1, 2024	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer
30 days after receipt of written initial offer from CMS (March 2nd if the offer is made by CMS on February 1, 2024)	Statutory deadline for the Primary Manufacturer to accept the initial offer or submit a written counteroffer to CMS
30 days after receipt of the manufacturer counteroffer (April 1st if the manufacturer counteroffer is made on March 2, 2024)	Date by which CMS will provide a written response accepting or rejecting the manufacturer counteroffer
Date that the Primary Manufacturer's written counteroffer is not accepted by CMS through June 28, 2024 (the last business day that is fifteen days prior to July 15, 2024)	Negotiation meetings (in-person, virtual, or hybrid, maximum of three possible meetings), if necessary
July 15, 2024	Date by which CMS will issue a "Notification of Final Maximum Fair Price Offer" to the Primary Manufacturer, if the written initial offer or Primary Manufacturer written counteroffer was not accepted and an MFP was not agreed upon in association with the negotiation meetings
July 31, 2024	Date by which the Primary Manufacturer must respond to (i.e., accept or reject) CMS' "Notification of Final Maximum Fair Price Offer," if applicable
July 31, 2024	Statutory deadline for all negotiations to end; CMS will notify the Primary Manufacturer of any failure to meet the deadline and the possible consequences thereof if agreement upon the MFP is not reached by July 31, 2024
August 1, 2024	Statutory end of negotiation period

To formalize agreement on an MFP, CMS and the Primary Manufacturer both sign an Addendum to the Agreement (described in sections 40.3 and 60.4 of this revised guidance) that sets forth the agreed-upon MFP. When CMS prepares a written offer, CMS also completes the Addendum with the offered MFP and sends the Addendum along with the written offer to the Primary Manufacturer via CMS HPMS. If the Primary Manufacturer accepts the written offer, they will sign the Addendum after which CMS will countersign the Addendum. Similarly, a

[71] These dates are contingent on CMS and the Primary Manufacturer meeting the deadlines described in this revised guidance and in statute. If the Primary Manufacturer is delayed in meeting one or more deadlines, CMS will continue to engage in the negotiation process and will take the time to complete the established process as described in this section. If a statutory deadline is missed, the Primary Manufacturer may be subject to a civil monetary penalty or excise tax.

Primary Manufacturer's written counteroffer is not considered complete unless the Primary Manufacturer submits a complete response to the Drug Price Negotiation Process ICR in CMS HPMS, submits an Addendum for the MFP consistent with the counteroffer amount in CMS HPMS, and signs that Addendum. If CMS accepts the written counteroffer, it will countersign the Addendum.[72]

If CMS and the Primary Manufacturer do not agree to an MFP by the statutory end of the negotiation period, the Primary Manufacturer will enter a period during which an excise tax potentially may be assessed. As described in 26 U.S.C. § 5000D(b)(2) and § 5000D(c), the Primary Manufacturer can end the period during which the excise tax may apply by agreeing to an MFP, as described in section 60.8 of this revised guidance, or can meet the statutory criteria for the suspension of tax or may terminate its Agreement in the manner described in section 40.6 of this revised guidance, which includes sending a notice terminating all of their applicable agreements under the Medicare and Medicaid programs and establishing that none of the Primary Manufacturer's drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act.

60.5 Application of the MFP Across Dosage Forms and Strengths

An MFP that is agreed upon as described in section 60.4 of this revised guidance establishes one price for the selected drug. In accordance with section 1196(a)(2) of the Act, CMS has the administrative duty to establish procedures to compute and apply the MFP across different dosage forms and strengths of the selected drug and not based on the specific formulation or package size or package type of such drug.

As described in section 60.1 of this revised guidance, the MFP will reflect a single price for the selected drug per 30-day equivalent supply. To ensure that the MFP is made available to MFP-eligible individuals at the point of sale (and to pharmacies, mail order services, or other dispensers, with respect to such MFP-eligible individuals), however, CMS will publish the MFP at the per-unit (e.g., tablet) level for each NDC-9 and NDC-11 associated with the selected drug.

The following methodology will be used to apply the single MFP across NDC-9s for a 30-day equivalent supply and to calculate an MFP per unit for each NDC-9 of the selected drug. CMS will use a methodology that scales the MFP per unit based on price differentials across different dosage forms and strengths. For initial price applicability year 2026, CMS will use the WAC of the selected drug in this calculation. CMS will first calculate an annual WAC per unit cost for each NDC-11 included on the list of NDC-11s of the selected drug in the CMS HPMS, inclusive of any NDC-11s added by the Primary Manufacturer (see section 40.2 of this revised guidance), from the manufacturer-submitted quarterly WAC per unit and unit volume data, to account for potential variation in unit volume across quarters. The annual WAC per unit for each NDC-11 will then be converted into an amount for a 30-day equivalent supply (using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2)), so that the WAC will be comparable to the negotiated single MFP. CMS will then aggregate the WAC per 30-day equivalent supply for each NDC-11 into a WAC per 30-day supply for each NDC-9 of the selected drug. The WAC per 30-day equivalent supply for each NDC-9 will then be used to calculate a WAC price ratio

[72] In the event that this functionality is delayed in CMS HPMS, CMS will specify an alternative approach for sharing the Addendum in writing.

for each NDC-9 of the selected drug. The ratio derived from the WAC per 30-day equivalent supply for each NDC-9 will then be multiplied by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each NDC-9 of the selected drug. Lastly, to determine the per unit MFP for an NDC-9, CMS will convert from an MFP for a 30-day equivalent supply to an MFP per unit based on the average number of units in a 30-day equivalent supply.

The following steps provide additional detail regarding the approach CMS will use:

1. For each NDC-11 and calendar quarter, CMS will divide the WAC quarterly units by the total WAC annual units (from- manufacturer submitted data) and multiply this quotient by the quarterly WAC per unit.
    - Note: CMS will use the WAC unit cost for the period beginning January 1, 2022 and ending December 31, 2022 for purposes of this calculation to align with the time period of data used to calculate the ceiling for the MFP.
2. For each NDC-11, CMS will then sum the amounts calculated in step 1 to calculate the annual WAC per unit.
3. For each NDC-11, CMS will divide the quantity dispensed by the total 30-day equivalent supply, both calculated from 2022 PDE data, to calculate the average number of units per 30-day equivalent supply.
4. For each NDC-11, CMS will multiply the WAC per unit calculated in step 2 by the average number of units per 30-day equivalent supply calculated in step 3 to calculate the WAC per 30-day equivalent day supply for that NDC-11.
5. For each NDC-11, CMS will divide the total 30-day equivalent supply for that NDC-11 by the total 30-day equivalent supply across all applicable NDC-11s within an NDC-9 and then multiply this quotient by the amount calculated in step 4.
6. For each NDC-9, CMS will then sum amounts calculated in step 5 across all NDC-11s to calculate the WAC per 30-day equivalent supply for that NDC-9.
7. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s and then multiply this quotient by the amount calculated in step 6.
8. CMS will then sum amounts calculated in step 7 across all NDC-9s of the selected drug to calculate the WAC per 30-day equivalent supply for the selected drug.
9. For each NDC-9, CMS will then divide the WAC per 30-day equivalent day supply for that NDC-9 calculated in step 6 by the WAC per 30-day equivalent supply for the selected drug calculated in step 8 to calculate the WAC per 30-day equivalent supply ratio for that NDC-9.
10. For each NDC-9, CMS will multiply the single MFP for the selected drug by the relative WAC per 30-day equivalent supply ratio for that NDC-9 calculated in step 9 to calculate the MFP per 30-day equivalent supply for that NDC-9.
11. For each NDC-9, CMS will divide the MFP per 30-day equivalent supply for that NDC-9 calculated in step 10 by the quotient of the total number of units dispensed divided by the total 30-day equivalent supply to calculate the MFP per unit (e.g., tablet).

CMS will include the MFP per unit price for each NDC-9 of the selected drug, calculated in step 11 of this section 60.5 of this revised guidance, along with corresponding NDC-11 package prices (determined by multiplying the NDC-9 unit price by the number of units per NDC-11 package), in the publication of MFPs as described in section 60.6 of this revised guidance. CMS

recognizes there may be other ways to apply the MFP to dosage forms and strengths and will monitor whether this policy serves the intent of the Negotiation Program. As noted throughout this revised guidance, the policies described for the Negotiation Program are for initial price applicability year 2026, and CMS may consider additional policies for future years of the Negotiation Program.

60.5.1 Application of the MFP to New NDAs / BLAs or NDCs

Based on the definition of a qualifying single source drug described in section 30.1 of this revised guidance, if the Primary Manufacturer for a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient after the drug has been selected, CMS requires that the MFP apply to drug or biological products marketed pursuant to the new NDA or BLA. Similarly, after the drug is selected, if the Primary Manufacturer for such drug receives approval or licensure for a new drug or biological product or NDC that is marketed pursuant to a supplement to an existing NDA or BLA, CMS requires that the MFP apply to such new drug or biological product. Additionally, an NDC that has been marketed pursuant to an applicable NDA or BLA prior to drug selection may lack sufficient PDE or WAC data in 2022 to apply the MFP across that dosage form and strength as described above. To apply the MFP to a new NDC that is marketed for the first time after the MFP is negotiated for a selected drug (including before or after the start of the initial price applicability year) or to an NDC that is marketed prior to MFP negotiation but which lacks either sufficient PDE unit data for calendar year 2022 or sufficient WAC data for calendar year 2022 for CMS to apply the MFP to that dosage form and strength as described above, CMS will determine whether there is an existing, comparable NDC to which the MFP for the selected drug has been applied. If a comparable NDC exists, CMS will impute the quotient of total quantity dispensed to 30-day equivalent supply based on the FDA-approved label associated with the new NDC and will use the same WAC ratio that was calculated for the existing NDC to apply the MFP to the new NDC.

If a comparable NDC does not exist, CMS will impute the quotient of total quantity dispensed to 30-day equivalent supply based on the FDA-approved label associated with the new NDC but will use a WAC ratio of 1.0 to apply the MFP to the new NDC.[73]

60.6 Publication of the MFP

In accordance with section 1191(d)(6) and section 1195(a)(1) of the Act, CMS will publish by September 1, 2024, the MFP for each drug selected for initial price applicability year 2026 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file, and the explanation for the MFP (published at a later date – see section 60.6.1 of this revised guidance). The MFP file will contain the single MFP for a 30-day equivalent supply of the selected drug, the NDC-9 per unit price, and NDC-11 per package price and will be updated annually to show the inflation-adjusted MFP for the selected drug. CMS will also publish on the CMS website when a drug is no longer a selected drug and

[73] While this guidance is focused on initial price applicability year 2026, CMS notes that in future years, renegotiation of the MFP might be appropriate in the event of certain new NDCs that represent material changes to the selected drug, such as where the new NDC is sought due to changes in the selected drug that result in the addition of a new indication. CMS will provide additional information in the future on renegotiation, which will be implemented for initial price applicability year 2028 and subsequent years, in accordance with the statute.

the reason for that change, and when an MFP between a Primary Manufacturer and CMS is not agreed upon.

60.6.1 Explanation for the MFP

Section 1195(a)(2) of the Act requires CMS to publish an explanation for the MFP no later than March 1 of the year prior to the initial price applicability year, which will be March 1, 2025 for initial price applicability year 2026. CMS will strive to publish these explanations earlier than March 1, 2025, if feasible. The explanation will focus on the section 1194(e) data that had the greatest impact in determining the MFP and include a discussion of the other section 1194(e) data, as applicable. It will also note any data or circumstances that may be unique to the selected drug. Alongside the narrative explanation, CMS will release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS will develop and publish the public explanation of the MFP in accordance with the confidentiality policy described in section 40.2 of this revised guidance.

If an agreement for an MFP is not reached for a selected drug, neither an MFP nor a public explanation of the MFP will be published. Instead, CMS will indicate on the CMS website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug. In circumstances where an MFP is finalized after the statutory deadline for the conclusion of negotiations, the MFP and the public explanation of the MFP will be posted in accordance with section 60.8 of this revised guidance.

60.7 Exclusion from the Negotiation Process Based on Generic or Biosimilar Availability

In accordance with section 1192(c)(2) of the Act and subject to the timeline and situations discussed in section 70, a selected drug will no longer be subject to the negotiation process, with respect to its initial price applicability year, if CMS determines that at least one generic drug or biosimilar biological product satisfies the following criteria: (1) it is approved under section 505(j) of the FD&C Act with at least one dosage form and strength of the selected drug as the listed drug or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product, and (2) it is marketed pursuant to such approval or licensure. The approach CMS will take to make this determination is described in section 70 of this revised guidance.

When the drug is no longer subject to the negotiation process based on the criteria in section 1192(c)(2) of the Act, the selected drug will continue to be considered a selected drug with respect to such initial price applicability year with respect to the number of negotiation-eligible drugs on the list published under section 1192(a) of the Act (see section 70 of this revised guidance for additional details).

60.8 Establishment of MFPs After the Negotiation Deadline

Sections 1194(b)(2) and 1191(d)(5)(C) of the Act contemplate that agreement upon an MFP must be reached for initial price applicability year 2026 by August 1, 2024 in order to avoid potential imposition of an excise tax. If negotiations have not ended by this date, the Primary Manufacturer may be subject to an excise tax. As a general matter, if the Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, CMS will continue to engage in the negotiation process described in section 60.4 of this revised guidance.

Certain actions or delays by the Primary Manufacturer may delay the process such that the MFP is established after the end of the negotiation period. If this occurs, in accordance with section 1194(b)(1) of the Act, CMS will follow timelines consistent with the negotiation process established in this revised guidance and take the time to complete the established process so described as appropriate for the selected drug. Likewise, certain actions by the Primary Manufacturer may delay the negotiation process to such an extent that a selected drug has a change in status that is material to CMS' statutory obligations under the negotiation process. If this occurs, in accordance with section 1194(b)(1), when CMS initiates or resumes the negotiation process, CMS will apply the consistent methodology and process with respect to the selected drug based on its status at the time the negotiation process occurs, including beginning in 2028 which may have potential implications with respect to the renegotiation process. Guidance about the renegotiation process will be forthcoming for future years of the Negotiation Program.

If the manufacturer and CMS have completed each step of the negotiation process as detailed in section 60.4 of this revised guidance, including CMS' issuance of a "Notification of Final Maximum Fair Price Offer" and then, after the statutory end of the negotiation period, the Primary Manufacturer of a selected drug wishes to agree to an MFP, the Primary Manufacturer must notify CMS in writing that it would like to accept the last offer of an MFP from CMS, as reflected in the "Notification of Final Maximum Fair Price Offer." In accordance with section 1195(b)(2) of the Act, in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, CMS shall publish the MFP no later than 30 days after the date such MFP is so determined. In accordance with section 60.6 of this revised guidance, CMS will publish the MFP and the MFP explanation on the CMS website. CMS will follow timelines consistent with the established process for publishing the public explanation of the MFP and will not expedite its timeline due to late action from the Primary Manufacturer.

70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

In accordance with section 1192(c) of the Act, a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations discussed below, if CMS determines (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure.

The approval (or licensure, as applicable) and marketing of an authorized generic drug (which includes authorized generic drugs and certain biological products as defined in section 1192(e)(2) of the Act) would not qualify as meeting the statutory requirement that a generic drug or a biosimilar biological product is being marketed. In accordance with section 1192(e)(2)(B)(i) of the Act, an authorized generic drug as defined in section 505(t)(3) of the FD&C Act is treated as the same qualifying single source drug as a qualifying single source drug that is the listed drug, for the purposes of the Negotiation Program. Likewise, section 1192(e)(2)(B)(ii) of the Act indicates that the same rule applies to a biological product that is approved under section 351(a)

of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under different labeling or packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark.

The determination whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list will be informed by CMS' review of PDE and AMP data for the generic drug or biosimilar biological product for which the selected drug is the listed drug or reference product on a monthly basis as described below. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of the generic drug or biosimilar biological product is engaging in bona fide marketing of that drug or product.

After the selected drug is removed from the selected drug list, CMS will monitor the manufacturers of such generic drugs or biosimilar biological products to ensure they continue to engage in bona fide marketing of the generic or biosimilar biological product based on the process described in section 90.4 of this revised guidance.

Starting in October 2023, and repeated each month thereafter, CMS will take the following approach in its review of data to inform its determination whether the statutory criteria in sections 1192(c)(1)(A) and 1192(c)(1)(B) of the Act for an approved generic drug or licensed biosimilar to be marketed pursuant to such approval or licensure are being met.

First, CMS will use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar biological product is approved or licensed for any strength(s) or dosage form(s) of a selected drug for initial price applicability year 2026.

Second, if CMS determines that a generic drug or biosimilar biological product has been approved or licensed, CMS will begin by reviewing the PDE and AMP data with dates of service during the most recent 12-month period available to determine if the manufacturer of the generic drug or biosimilar biological product has engaged in bona fide marketing of that drug or product. For example, when CMS performs this assessment in October of 2023, CMS will use PDE and AMP data with dates of service from October 2022 through September 2023. When CMS performs this assessment in November 2023, CMS will use PDE and AMP data for dates of service from November 2022 through October 2023.

The determination whether a generic drug or biosimilar is being bona fide marketed is a totality-of-the-circumstances inquiry that will not necessarily turn on any one source of data. Additional relevant factors may include whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug, as articulated further in section 90.4.

Per section 1192(c)(2) of the Act, if CMS makes a determination regarding generic drug or biosimilar biological product availability on or after the selected drug publication date, and

before the end of or during the negotiation period for an initial price applicability year, the selected drug will not be subject to the negotiation process for the negotiation period, and an MFP will not be established. Accordingly, for initial price applicability year 2026, if CMS makes this determination between September 1, 2023, and August 1, 2024, the drug will remain a selected drug through 2026, but no MFP will apply and the drug will not be replaced with another selected drug.

In accordance with section 1192(c)(1) of the Act, a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines the statutory criteria in section 1192(c) are met. Accordingly, if CMS makes this determination between August 2, 2024, and March 31, 2026, for a drug selected for initial price applicability year 2026, then the drug will cease to be a selected drug on January 1, 2027, and the MFP will apply for 2026. If CMS makes this determination between April 1, 2026, and March 31, 2027, then the selected drug will cease to be a selected drug on January 1, 2028, and the MFP will apply for 2026 and 2027. These results are summarized in the following table:

Date on which CMS determines that a generic drug or biosimilar biological product is approved and marketed	**Result with respect to selected drug for the Negotiation Program**
September 1, 2023 through August 1, 2024 (which includes the Negotiation Period for the initial price applicability year 2026)	Selected drug remains a selected drug for initial price applicability year 2026, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2027.
August 2, 2024 through March 31, 2026	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026; selected drug ceases to be a selected drug on January 1, 2027.
April 1, 2026 through March 31, 2027	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026 and calendar year 2027; selected drug ceases to be a selected drug on January 1, 2028.

Without regard to whether the Primary Manufacturer decides to execute an Agreement as discussed in section 40.1 of this revised guidance, to terminate an Agreement as discussed in section 40.6, or to transfer ownership of the selected drug as discussed in section 40.7, a selected drug remains a selected drug until CMS determines otherwise under the criteria set forth in section 1192(c) of the Act.

In all cases, after CMS determines the statutory criteria in section 1192(c) for generic competition are met for a selected drug, CMS will publish such information on the CMS website.

80. MFP-Eligible Individuals

For initial price applicability year 2026, in accordance with section 1191(c)(2) of the Act, the term “maximum fair price eligible individual” means, with respect to a selected drug, the

following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including an Employer Group Waiver Plan), if Part D coverage is provided under such plan for such selected drug. The MFP is not required to be made available to a Medicare beneficiary who uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash.[74] For initial price applicability year 2026, CMS does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to MFP eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan.

90. Manufacturer Compliance and Oversight

In accordance with section 1196(b) of the Act, CMS will monitor compliance by a Primary Manufacturer with the terms of the Agreement and establish a mechanism through which violations of such terms shall be reported.

90.1 Monitoring of Manufacturer Compliance

CMS will closely monitor the Primary Manufacturer's compliance with the terms of the Agreement and other aspects of the Negotiation Program. Following the publication of selected drugs for each initial price applicability year, CMS will provide information about the negotiation process to the Primary Manufacturer of each selected drug (see section 40 of this revised guidance for additional details). CMS anticipates this information will include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information.

During the negotiation period, CMS will track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer. To facilitate successful Negotiation Program operations and support manufacturer compliance with Program requirements, CMS will issue reminder letters prior to manufacturer deadlines with warnings of potential applicability of excise taxes (see 26 U.S.C. § 5000D for additional information regarding the excise tax) or CMPs (see section 100 of this revised guidance), written requests for corrective action when applicable (see section 40.2.3 of this revised guidance), written notification that a Primary Manufacturer may be subject to enforcement action as applicable, and written confirmation that a Primary Manufacturer may no longer be subject to enforcement action as applicable.

Failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program may result in potential excise tax liability (see 26 U.S.C. § 5000D). As described in section 100 of this revised guidance, failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in CMPs.

[74] CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.

90.2 Monitoring of Access to the MFP

In accordance with section 1193(a)(3)(A) of the Act, under the Agreement with CMS with respect to a price applicability period, access to the MFP with respect to such a selected drug shall be provided by the Primary Manufacturer to MFP-eligible individuals at the pharmacy, mail order service, or other dispenser at the point of sale, and to the pharmacy, mail order service, or other dispenser with respect to such MFP-eligible individuals who are dispensed the selected drug.

Further, in accordance with section 1193(a)(5) of the Act, which requires that the manufacturer comply with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program, and section 40.4 of this revised guidance, CMS requires that the Primary Manufacturer establish safeguards to ensure the MFP is available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers on units of the selected drug for which there are Secondary Manufacturers. CMS reiterates that the requirement for the Primary Manufacturer to provide access to the MFP applies to all sales of the selected drug by a Secondary Manufacturer to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as discussed in section 80 of this revised guidance.

As described in section 40.4 of this revised guidance, CMS is considering the potential to engage with an MTF to facilitate the exchange of data between supply chain entities to support the verification of MFP eligibility of an individual who is dispensed a selected drug. Each component of the pharmaceutical supply chain may have a role in making the MFP available to MFP-eligible individuals, but it is ultimately the Primary Manufacturer's responsibility to ensure access to the MFP. There are various methods by which dispensing entities and MFP-eligible individuals can determine whether they are accessing the MFP for a selected drug.

For example, under section 1195(a) of the Act, the MFP for a selected drug will be published by CMS, giving the public and other interested parties an opportunity to know the MFP for each selected drug, as well as the explanation for each MFP (see section 60.6 of this revised guidance for additional details). Under section 1191(d)(6), the MFPs for selected drugs for initial price applicability year 2026 must be published by September 1, 2024. In addition, CMS anticipates that pharmaceutical database compendia will publish the MFPs for selected drugs such that they would become more knowable and accessible to pharmaceutical purchasers. CMS believes such transparency of the MFPs for selected drugs will help dispensing entities and MFP-eligible individuals to know the MFP for a selected drug and determine whether they are able to access the MFP.

In accordance with section 1196(a)(3)(A) of the Act, as well as section 1196(b), which requires that the Secretary establish a mechanism by which violations of the terms of the Agreement shall be reported, CMS will establish procedures for reporting suspected violations related to access to the MFP with respect to MFP-eligible individuals who are enrolled in Medicare Part D plans and the pharmacies, mail order services, and other dispensers that provide selected drugs to MFP-eligible individuals. As part of this process, CMS may establish a toll-free phone line and email box where an individual or a dispenser could communicate information to CMS regarding an incident in which the MFP was not provided to an MFP-eligible individual or the applicable

pharmacy, mail order service, or other dispenser. CMS anticipates the submissions would likely include the name of the individual reporting the incident, the nature of the incident, the date the incident occurred, the name of the drug, the manufacturer of the drug, and contact information for follow-up.

Upon receipt of a report of a suspected violation, CMS will review the submissions, investigate reports of potential noncompliance, and if appropriate, impose CMPs on the Primary Manufacturer if CMS determines the Primary Manufacturer failed to provide an MFP-eligible individual or an eligible dispenser access to the MFP for the selected drug, including in cases where there are one or more Secondary Manufacturers of the selected drug. CMS would also expect manufacturers and other interested parties to report instances in which a dispenser was not passing through the MFP to an MFP-eligible individual, or a dispenser was extending the MFP to non-MFP-eligible individuals.

As described in section 40.4.1 of this revised guidance and consistent with section 1193(d) of the Act regarding the manufacturer's Agreement with CMS, a manufacturer with a Pharmaceutical Pricing Agreement (PPA) with the Secretary under the 340B program is not required to provide a 340B covered entity with access to the MFP of a selected drug with respect to an MFP-eligible individual who is eligible to be dispensed such selected drug at the covered entity if the 340B ceiling price is lower than the MFP for such selected drug.

CMS is also aware that it is conceptually possible for an entity that meets the statutory definition of a manufacturer, but that is not the Primary Manufacturer or a Secondary Manufacturer, to market one or more drug or biological products pursuant to one or more NDA(s) or BLA(s) included in the selected drug. For example, it is possible for an entity to purchase one or more drug or biological products included in the selected drug from a wholesaler, repackage or relabel such products, and then re-market them pursuant to one or more NDA(s) or BLA(s) included in the selected drug. CMS believes it would be appropriate for the MFP to be made available to all MFP-eligible individuals and to all pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed units of the selected drug. However, for initial price applicability year 2026, CMS is limiting the scope of Primary Manufacturer responsibility to provide access to the MFP for the selected drug to units of such drug sold by the Primary Manufacturer or a Secondary Manufacturer. CMS will monitor to determine if there are sales of selected drug to MFP-eligible individuals by manufacturers other than Primary Manufacturer and Secondary Manufacturers and consider whether other mechanisms are needed to promote access to MFP to Medicare-eligible individuals in these circumstances. CMS continues to seek feedback on how it might achieve this goal, interested parties can send feedback on this topic to IRARebateandNegotiation@cms.hhs.gov.

90.3 26 U.S.C. Section 5000D Excise Tax on Sale of Designated Drugs

The IRS will administer the excise tax. CMS understands that the Treasury Department will issue guidance relating to the excise tax in the coming weeks.

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

If CMS determines that either:

(1) a potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026 because any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic drugs or biosimilar biological products that CMS determined are approved or licensed and marketed based on the process described in section 30.1 of this revised guidance, or

(2) a selected drug is no longer subject to the negotiation process and ceases to be a selected drug because (a) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (b) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure in accordance with section 1192(c) of the Act and under the process described in sections 60.7 and 70 of this revised guidance,

then CMS will monitor, after such an above determination is made, whether meaningful competition continues to exist in the market by ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing. Such monitoring by CMS may include, but is not limited to, whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug.

CMS is aware that marketing or other agreements between the Primary Manufacturer and generic drug or biosimilar manufacturers may limit the availability of the generic drug or biosimilar for purchase through the pharmaceutical supply chain, and CMS will attempt to identify when such agreements exist as a factor in determining whether bona fide marketing exists, although such agreements would not by themselves be dispositive of that determination. CMS notes that any agreements limiting the availability of a selected drug may be subject to scrutiny and potential enforcement under antitrust laws (including laws prohibiting unfair methods of competition) as well as laws prohibiting unfair or deceptive acts or practices in or affecting commerce.

In addition, CMS will analyze the share of generic drug or biosimilar biological product units identified in PDE data as a percentage of total units of Part D expenditures, as well as whether manufacturers are reporting units of the selected drug as part of their AMP reporting responsibilities under section 1927(b)(3)(A) of the Act, and the trend in reporting of such AMP units. CMS reserves the right to also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar.

100. Civil Monetary Penalties

In accordance with section 1197 of the Act, Primary Manufacturers of selected drugs that enter into an Agreement may be subject to CMPs for (1) failure to ensure access to a price that is less than or equal to the MFP for MFP-eligible individuals and pharmacies, mail order services, and

other dispensers who dispense the selected drug with respect to MFP-eligible individuals, (2) failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but has since undergone negotiation, as described in section 1192(f)(4) of the Act, (3) violation of certain terms of the Agreement, and (4) the provision of false information as described in section 1197(d) of the Act.

CMS' primary goal is to successfully administer all aspects of the Negotiation Program; CMS intends to exercise the authority to impose CMPs for instances of noncompliance that substantively obstruct negotiation processes and/or availability of the MFP Such instances may include, but are not limited to, failure to make the MFP available to MFP-eligible individuals; failure to provide timely, complete, and accurate information that is necessary to execute the negotiation process or other administrative or monitoring functions of the Negotiation Program; repeated violations of the Agreement or other Negotiation Program requirements; or egregious and/or knowing violations of Negotiation Program requirements.

Broadly, CMS is establishing a structure for enforcement actions that:

1. Is within CMS' statutory authority,
2. Is not punitive in response to immaterial or other instances of noncompliance that are not substantive,
3. Can be applied consistently across applicable instances of Primary Manufacturer noncompliance, and
4. Facilitates the ability to successfully engage in all components of the negotiation process within the established statutory timeframes.

This revised guidance addresses violations by a Primary Manufacturer for failure to ensure access to a price for a selected drug less than or equal to the MFP, violation of terms of the Agreement, and provision of false information as related to the aggregation rule of the Small Biotech Exception and the Biosimilar Delay Rule. This revised guidance does not address failure to pay a rebate for a biological product pursuant to section 1192(f)(4) of the Act, as this topic will be addressed in future guidance. CMS provides details about the process for CMP imposition in section 100.4 of this revised guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP
In accordance with section 1197(a) of the Act, CMS may impose a CMP on a Primary Manufacturer of a selected drug that has entered into an Agreement with CMS upon failure to provide access to a price that is less than or equal to the MFP to MFP-eligible individuals dispensed the selected drug and to pharmacies, mail order services, or other dispensers with respect to MFP-eligible individuals who are dispensed the selected drug, including the failure to do so in connection with sales of the selected drug by a Secondary Manufacturer. CMS will be monitoring the WAC in relation to other pricing metrics. Upon discovery and confirmation of a failure to make the MFP available, CMS will send the Primary Manufacturer a Notice of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. CMS will establish an informal process in which the Primary Manufacturer will have 10 business days to respond to the Notice of Potential Noncompliance to provide additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration. CMS will consider the materials

provided by the Primary Manufacturer when determining the Primary Manufacturer's CMP liability.

If the Primary Manufacturer fails to ensure access to a price less than or equal to the MFP, the statute provides for a CMP equal to 10 times the amount equal to the product of the number of units of such drug so dispensed (during such year) and the difference between the price for such drug made available (for such year by such manufacturer) to MFP-eligible individuals and the MFP for such drug for such year. For the purposes of calculating this CMP, CMS will use the amount that is equal to the required pass through of the MFP described in section 40.4 of this revised guidance. As described in section 40.5 of this revised guidance, CMS will monitor for compliance and audit, as needed, to ensure that the MFP or a price lower than the MFP is being made available for the selected drug.

100.2 Violations of the Agreement

Pursuant to section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Agreement with CMS under section 1193 of the Act that fails to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program pursuant to section 1193(a)(5) or fails to provide the information required under section 1193(a)(4) may be subject to a CMP of $1,000,000 for each day of such violation. In applying CMPs for Primary Manufacturer violations of the Agreement, CMS intends to use discretion such that CMPs are reserved for instances of substantive noncompliance. Examples of such violations are shown in the table below. Note that these examples are not an exhaustive list of violations that could warrant CMPs. CMS reserves the authority to issue CMPs for other violations as required to effectively administer and monitor the Negotiation Program.

Category	Example of Substantive Violations
Manufacturer Information Submission	• Failure to submit data required under section 1194(e)(1) of the Act, including failure to engage in requested corrective action to mitigate such failures. • Omissions or inaccuracies of manufacturer-submitted information that is critical to the negotiation processes (e.g., non-FAMP data from the Primary Manufacturer, including non-FAMP data for a selected drug sold by any Secondary Manufacturer(s), required for ceiling calculation) or other efforts to administer or monitor the Negotiation Program (e.g., information requested during an audit), including failure to engage in requested corrective action to mitigate such omissions or inaccuracies. • Submission of false information that interferes with the negotiation process (e.g., submission of false data on unit costs of production). • Knowing submission of false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) for the Small Biotech Exception. • Knowing provision of false information under procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Biosimilar Delay.
MFP Availability	• Failure to make the MFP available to MFP-eligible individuals, and to pharmacies, mail order services, or other dispensers (see section 100.1 of this revised guidance) • Failure to process timely and complete reimbursement under a retrospective reimbursement structure as described in section 40.4 of this revised guidance.

As an example of when CMS would impose a CMP, consider the following. As described in section 40.2 of this revised guidance, information on non-FAMP for each applicable quarter (as described in section 50.1.1 of this revised guidance) for each NDC-11 of the selected drug for the applicable period will be due to CMS as part of the Negotiation Data Elements ICR no later than October 2, 2023 for initial price applicability year 2026. If the Primary Manufacturer fails to timely submit the required non-FAMP information, including the non-FAMP information for each NDC-11 of a selected drug for which there is a Secondary Manufacturer, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the applicable submission deadline (e.g., October 3, 2023 for initial price applicability year 2026) as the first day of violation with each additional day of violation thereafter counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. In the event a manufacturer never provides the required information, the daily CMP will continue to accrue until the end of the negotiation period (i.e., the final deadline for reaching an agreed upon MFP). Upon reaching that deadline, the manufacturer may also be subject to a potential excise tax for failing to reach an agreed upon MFP pursuant to 26 U.S.C. § 5000D(b)(2).

CMS may require additional information to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. When applicable, CMS will provide a written request to the Primary Manufacturer with details for such requests, including a date by which any requested information must be submitted. CMS is committed to providing Primary Manufacturers with reasonable timeframes to accommodate these information requests. CMS will consider written requests for deadline extension submitted no later than three calendar days prior to the initial deadline. Extension requests must include a reasonable basis for requiring the extension as determined by CMS. Only one extension, if applicable, will be granted for each request. Manufacturers that fail to comply with requests for information required to administer or monitor compliance with the Negotiation Program on or before the due date may be subject to a CMP.

In the event the manufacturer does not meet the final established deadline to provide the requested information and CMS determines a CMP is warranted, the CMP will begin to accrue beginning on the day after the due date. For example, if CMS requests information for monitoring purposes by November 15, 2027, day one of the violation would be November 16, 2027. Each additional day of violation thereafter will be counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. The CMP will not include the day the information is submitted. Because the day of data submission is not included in CMP calculation, should a Primary Manufacturer submit the requested information on the day after the deadline, no CMP will be imposed.

To facilitate program operations and support manufacturer compliance, CMS will provide the Primary Manufacturer with: (1) written reminders of impending submission deadlines, including warning of potential liability for a CMP for submission violations; and (2) Notification of Potential Noncompliance, if applicable, and the applicable next steps (see, for example, sections

40.2.3 and 100.1 of this revised guidance). If CMS determines a violation warrants a CMP, CMS will follow the procedures outlined in section 100.4 of this revised guidance to notify the Primary Manufacturer and initiate the CMP process.

A Primary Manufacturer that submits false Information that is required under the Agreement and interferes with the administration of the Negotiation Program will be out of compliance with the requirement to submit information and may be subject to this CMP. In instances of a Primary Manufacturer submitting false information that is required under the Agreement, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the established deadline for submission of information under the Agreement as the first day of violation with each additional day of violation thereafter counted until the day the Primary Manufacturer provides a complete and accurate submission of the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement.

100.3 Provision of False Information Related to the Small Biotech Exception and the Biosimilar Delay Rule

In accordance with section 1197(d) of the Act, if CMS determines that any manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) for the Small Biotech Exception, such manufacturer shall be subject to a CMP equal to $100,000,000 for each item of such false information. Likewise, if CMS determines that any Biosimilar Manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Biosimilar Delay, such manufacturer shall be subject to a CMP equal to $100,000,000 for each item of such false information.

CMS adopts a standard for "knowingly" that conforms with the Office of the Inspector General definition at 42 C.F.R. § 1003.110 in the application of other CMPs. Knowingly means that a manufacturer, for purposes of section 1197(d) of the Act for the Small Biotech Exception or a Biosimilar Manufacturer under section 1192(f)(1)(c) for the Biosimilar delay: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. Upon identifying instances of knowing submission of false information under either of these provisions, CMS will provide the Manufacturer with a CMP Notification detailing the final CMP amount and the basis for that amount, requesting payment, outlining the payment process, outlining the available appeals process, and establishing applicable deadlines for resolution.

100.4 Notice and Appeal Procedures

Where CMS makes a determination to impose a CMP, CMS will provide a written CMP Notification that the manufacturer has engaged in a substantive compliance violation and is subject to a CMP. As required by section 1128A of the Act, the CMP Notification will include the following:

- A description of the basis for the determination;
- The basis for the penalty;
- The Primary Manufacturer's right to a hearing (see below); and

- Information about where to file the request for a hearing.

In applicable cases (e.g., failure to provide required information), CMS will note the commencement date for a CMP accrual and alert the manufacturer that the daily CMP will continue to accrue until the period of noncompliance ends. CMS will send monthly noncompliance notices to the manufacturer during the noncompliance period to include the total amount of CMP accrued to date, the amount that will continue to accrue should the violation continue, and required actions on the part of the Primary Manufacturer to mitigate the noncompliance period (e.g., submission of required information), if applicable.

To operationalize the CMP appeal process in the Negotiation Program, CMS is adopting the existing procedures as codified in 42 C.F.R. section 423 subpart T: Appeal Procedures for Civil Money Penalties (see § 423.1000 through § 423.1094) that currently apply to Part D sponsors and to manufacturers under the Coverage Gap Discount Program. Pursuant to this appeals process, the manufacturer will have 60 calendar days from the date of receipt of the CMP Notification to request a hearing (§ 423.1020). The date of receipt is defined as the calendar day following the day on which the CMP Notification is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act and operationalized by 42 C.F.R. § 423 Subpart T will apply. As set forth in section 1128A(f), if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP funds will be deposited in accordance with section 1128A(f).

The CMP amount will cease to accrue once the manufacturer has demonstrated compliance with the requirement(s) at issue in the relevant CMP Notification. Following the end of the noncompliance period, and at the conclusion of any appeals process initiated by the Primary Manufacturer within 60 days of the CMP Notification, CMS will issue the final CMP Notification. As required by section 1128A of the Act, the final notification will add the following to the information included in the initial CMP Notification and monthly noncompliance notices:

- The final amount of the penalty;
- The date the penalty is due; and
- Instructions for submitting the CMP payment.

110. Part D Formulary Inclusion of Selected Drugs

In accordance with section 1860D-4(b)(3)(I) of the Act, Medicare Part D plans shall include each covered Part D drug that is a selected drug under section 1192 of the Act on Part D formularies during contract year 2026 and all subsequent years for which the MFP of the selected drug is in effect during the price applicability period.[75] Because the selected drug includes all dosage forms and strengths to which the MFP applies for initial price applicability year 2026, the statute requires that all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect be included on formulary. For contract year 2026, CMS will not implement explicit tier placement or utilization management requirements that

[75] As required by section 1860D-4(b)(3)(I)(ii) of the Act, nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under 42 C.F.R. § 423.120(b)(5)(iv) (or any successor regulation).

apply uniformly across selected drugs in all formularies, but intends to apply the process described below.

While CMS understands that not all selected drugs and drug classes will present Part D sponsors and their Pharmacy & Therapeutics Committees with the same formulary considerations and might not warrant the same formulary placement in all situations, CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.

CMS reminds Part D sponsors of the existing statutory and regulatory restrictions on formulary design. Sections 1860D-2(b)(2)(B) and 1860D-4(c)(1)(A) of the Act permit Part D sponsors to use formularies and tiered cost sharing in their benefit design, subject to certain limitations, and requires them to have a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate. Under section 1860D-11(e)(2)(D)(i) of the Act, CMS may approve a prescription drug plan only if the agency "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." In addition, 42 C.F.R. § 423.272(b)(2)(i) states: "CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Furthermore, 42 C.F.R. § 423.120(b)(2)(iii) requires each Part D plan formulary to "include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines." In addition, 42 C.F.R. § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must "base clinical decisions on the strength of scientific evidence and standards of practice." CMS maintains a robust clinical formulary review process to ensure that all Medicare Part D plans meet these and other applicable requirements. CMS reviews all formularies annually to ensure that each formulary passes the agency's clinical review criteria, which includes comprehensive evaluation of tier placement and all utilization management restrictions and criteria.

Given CMS' statutory obligation to monitor Medicare Part D plans' compliance with all applicable formulary requirements, CMS will use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers, (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class, (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy), or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

For this review, CMS will consider class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action. Specifically, as part of the contract year 2026 Part D formulary review and approval process, CMS will expect Part D sponsors to provide a reasonable justification to support the submitted plan design that includes

any of the practices noted above during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will only approve a Part D plan bid submitted by a Part D sponsor if the plan benefit package complies with those requirements.

120. Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs

This section of the guidance describes the application of Medicare Part B and Part D inflation rebates to selected drugs. As background, section 11101 of the IRA added a new section 1847A(i) to the Act to require that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Likewise, section 11102 of the IRA added a new section 1860D-14B to the Act, which requires that manufacturers of Part D rebatable drugs pay inflation rebates to Medicare for certain Part D rebatable drugs based on specific requirements and formulas.[76]

Given that initial price applicability year 2026 is limited to drugs for which there is Part D utilization, this revised guidance describes the interaction between the Negotiation Program and the Part D inflation rebate program. CMS will address the application of Part B inflation rebates to selected drugs in future guidance for initial price applicability year 2028.

The Part D drug inflation rebate program is applicable to certain drugs that meet the definition of a Part D rebatable drug and are dispensed under Part D and covered and paid for by Part D plans for each 12-month applicable period, starting with the applicable period beginning October 1, 2022. These rebates are paid by manufacturers to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

The Part B and Part D inflation rebate programs apply to selected drugs, regardless of the status of the drug as a selected drug. Alternatively said, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Part B and Part D inflation rebate program, as applicable. However, when a selected drug is no longer considered to be a selected drug, certain components of the applicable rebate amount formula are recalculated as discussed further below.

[76] CMS published initial guidance on both Part B and Part D inflation rebates on February 9, 2023, which includes more specific details on the operation of the Part B and Part D inflation rebate programs. See: https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf and https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.

The Part D inflation rebate calculation is based on changes in the AMP over time.[77] MFP is excluded from AMP and thus does not affect the rebate calculation.[78]

The statutory formula to determine the Part D drug inflation rebate amount owed by manufacturers for each Part D rebatable drug consists of various components, including the calculation of a benchmark period manufacturer price. This "benchmark period manufacturer price" is calculated based on a "payment amount benchmark period" for each Part D rebatable drug (established at section 1860D-14B(g)(3) of the Act for drugs first approved or licensed on or before October 1, 2021 and at section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021), and a "benchmark period CPI-U"[79] for each Part D rebatable drug (established at section 1860D-14B(g)(4) of the Act for drugs first approved or licensed on or before October 1, 2021 and section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021). The payment amount benchmark period is the basis for the calculation of the benchmark period manufacturer price. The benchmark period manufacturer price is based on a weighted AMP for the quarters in that period.

For the period of time before a Part D rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part D inflation rebate amount, if applicable, based on the Part D rebatable drug's applicable payment amount benchmark period and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, the statute at section 1860D-14B(b)(5)(C) specifies a different "payment amount benchmark period" and "benchmark period CPI-U" for each Part D rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period will be reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the January of the last year beginning during such price applicability period.

[77] Section 1860D-14B(g)(6) of the Act defines AMP to have the meaning, with respect to a Part D rebatable drug of a manufacturer, given in section 1927(k)(1) with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. Section 1927(k)(1) defines AMP, with respect to a covered outpatient drug of a manufacturer for a rebate period, to mean the average price paid to the manufacturer for the drug in the United States by (i) wholesalers for drugs distributed to retail community pharmacies, and (ii) retail community pharmacies that purchase directly from the manufacturer, subject to certain exclusions.

[78] Section 1927(k)(1)(B)(i)(VI), as amended by section 11001(b)(3) of the Inflation Reduction Act.

[79] CPI-U refers to the Consumer Price Index for all urban consumers (United States city average).

Appendix A: Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026

Email subject line:
Biosimilar Delay: Notice of Intent to Submit Initial Delay Request for Initial Price Applicability Year 2026

Body of email:
Dear CMS,

I, an authorized representative of [insert manufacturer name], am notifying CMS that my company is the manufacturer of a biosimilar biological product and we anticipate the reference product for our biosimilar biological product will be included in a negotiation-eligible drug with respect to initial price applicability year 2026 for the Medicare Drug Price Negotiation Program. My company reasonably believes the market entry of our biosimilar biological product meets the criteria for the special rule to delay selection and negotiation of the negotiation-eligible drug, described in section 1192(f) of the Social Security Act. Therefore, I am notifying CMS of my company's intent to request that CMS delay the inclusion of the negotiation-eligible drug that includes the reference product for our biosimilar biological product on the selected drug list for initial price applicability year 2026.

As part of this notification, I am providing the following information:

My job title:	[insert]
My email address:	[insert]
My phone number:	[insert]
My company's mailing address:	[insert]
My company's biosimilar biological product name:	[insert]
Product name of the reference product for my company's biosimilar biological product	[insert]

Signed,
[Insert name of authorized representative]

Appendix B: Template for the Initial Delay Request Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act), to negotiate maximum fair prices (MFPs)[80] for selected drugs. Under section 1192(f) of the Act (the "Biosimilar Delay"), the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug (as defined in section 1192(d) of the Act) that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA for the Biosimilar that has been submitted for review by FDA.

Please refer to the memo titled "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" (Initial Negotiation Program Guidance) for additional details regarding the implementation of the Biosimilar Delay for initial price applicability year 2026. This form serves as the template that a Biosimilar Manufacturer may complete to submit an Initial Delay Request with respect to initial price applicability year 2026.

Submission of the email described in that memo indicating the Biosimilar Manufacturer's intention to submit an Initial Delay Request for initial price applicability year 2026 and receipt of the fillable Initial Delay Request form template and request-specific Box folder should occur prior to completing this form.

Instructions

- Initial Delay Requests that are incomplete or not timely submitted will not be accepted. For an Initial Delay Request to be timely for initial price applicability year 2026, the Biosimilar Manufacturer must submit a complete Initial Delay Request to CMS no later than 11:59 pm PT on May 22, 2023. CMS will deem an Initial Delay Request to be complete if it includes a complete Initial Delay Request form using this fillable template and the following documentation:
    - All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

[80] In accordance with section 1191(c)(3) of the Social Security Act ("the Act"), maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

- The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
- Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.

- The data entry component of this submission should be completed by an individual authorized by the Biosimilar Manufacturer.
- The certification of the Initial Delay Request should be executed by (1) the chief executive officer (CEO) of the Biosimilar Manufacturer, (2) the chief financial officer (CFO) of the Biosimilar Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

CMS is relying on the fullness, accuracy, and completeness of the Biosimilar Manufacturer's submission to determine whether to approve the Initial Delay Request for initial price applicability year 2026. If the Biosimilar Manufacturer submits an Initial Delay Request that is not timely, complete, and accurate, the submission may adversely affect the Negotiation Program, including the process for selecting drugs for negotiation for initial price applicability year 2026.

Section 1: Identifying information

Identifying information for Biosimilar Manufacturer

Q1. Complete the following table with identifying information for the Biosimilar Manufacturer.

Field	Response
Entity Type	☐ Biosimilar Manufacturer
Entity name	
Employer Identification Number (EIN(s))	
Address	
Unique Identifier Assigned by CMS (P-number)	
Labeler Code(s)	

Identifying information on Biosimilar

Q2. Complete the following table with identifying information for the Biosimilar.

Field	Response
Product Name	

Active Ingredient	
NDC-9(s) (if applicable)	[optional, only if available]

Q3. List all applications for licensure for the Biosimilar under 351(k) of the Public Health Service (PHS) Act regardless of status (i.e., including applications that are approved, accepted for review, and submitted but not yet accepted for review). Leave approval date blank if license has not been approved.

Add additional rows for each application

Application Number	Submission Number	Application status	Approval Date [if licensed]	Indication	Dosage Form and Strength	Licensure planned before September 1, 2025?	Marketing planned before September 1, 2025?
nnnnnn	nnn	[Approved, Accepted for Review, Submitted]	MM/DD/ YYYY	Text	Text	[Yes/No]	[Yes/No]

Identifying information on Reference Product

Q4. Complete the following table with identifying information for the reference product for the Biosimilar.

Field	**Response**
Product Name	
Active Ingredient	
NDC-9(s)	

Q5. List the Biologic License Application (BLA) approved by the Food and Drug Administration (FDA) under section 351(a) of the PHS Act for the reference product for the Biosimilar.

Application Number	Submission Number	Approval Date	Indication	Dosage Form and Strength	Sponsor
nnnnnn	nnn	MM/DD/ YYYY	Text	Text	Text

Identifying information on Reference Manufacturer

Q6. Complete the following table with identifying information for the Reference Manufacturer.

Field	**Response**
Entity Type	☐ Reference Manufacturer
Entity name	

Employer Identification Number (EIN)	*[Optional, only if known]*
Address	*[Optional, only if known]*
Unique Identifier Assigned by CMS (P-number)	*[Optional, only if known]*
Labeler Code(s)	*[Optional, only if known]*

Section 2: Attestations to Requirements for Granting an Initial Delay Request

In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not delay inclusion of a biological product on the list of selected drugs if the Biosimilar Manufacturer meets any of the statutory criteria for an excluded manufacturer. Questions 7 through 9 address whether the Biosimilar Manufacturer is an excluded manufacturer.

Q7. Relationship between Biosimilar Manufacturer and Reference Manufacturer: In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not approve an Initial Delay Request if the Biosimilar Manufacturer is the same as the Reference Manufacturer or is treated as being the same as the Reference Manufacturer based on the aggregation rule in section 1192(f)(1)(C) of the Act. This aggregation rule provides, "all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer" for purposes of the Biosimilar Delay. Further, section 1192(f)(1)(C) of the Act establishes that "the term 'partnership' means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on" by two or more parties for the purposes of the Biosimilar Delay.

Read the following statement and check the box if accurate:

I confirm consistent with sections 1192(f)(1)(C) and 1192(f)(2)(D)(iv) of the Act that the Biosimilar Manufacturer submitting this request is not the same or is not treated as being the same as the Reference Manufacturer.	☐

Q8. Incentives: In accordance with section 1192(f)(2)(D)(iv)(II)(aa) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(aa) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that requires or incentivizes the Biosimilar Manufacturer to submit this or any other Initial Delay Request.	☐

Q9. Quantity Restriction: In accordance with section 1192(f)(2)(D)(iv)(II)(bb) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(bb) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.	☐

In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025. Questions 10 and 11 are relevant for this determination.

Q10. Licensure: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed before September 1, 2025. For the purposes of this Initial Delay Request, 'licensed' means approved by the FDA under section 351(k) of the PHS Act.

Select the following option that best describes the current licensure status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the Biosimilar has been licensed.	☐
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the FDA has accepted such application for review.	☐
(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and has not received a determination from FDA that such application has been accepted for review.	☐
(D) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has not submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act.	☐

Q11. Marketing: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be marketed before September 1, 2025.
Select the following option that best describes the current marketing status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar is currently marketed.	☐
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed but the Biosimilar Manufacturer expects it to be marketed by September 1, 2025.	☐

(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed and the Biosimilar Manufacturer does not expect it to be marketed by September 1, 2025.	☐

Section 3: Supporting Documentation

Q12. Manufacturing schedule: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, the manufacturing schedule for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation - Manufacturing schedule' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload the manufacturing schedule(s) for the Biosimilar submitted to the FDA for each application listed in Q3.

Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure is available for submission.	☐
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure.	☐

Q13. Disclosures: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Disclosures' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such disclosures.
Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the	☐

Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, are available for submission.	
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all such disclosures.	☐

Q14. Agreements:
In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Agreements' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such agreements.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.	☐

Section 4: Certification

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including to determine whether CMS should delay the selection of a biological product that would, absent this request, be included on the selected drug list for initial price applicability year 2026, as described in section 1192(f) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes []
No []

Contact Information

Field	Response
Name of the Person Responsible for the Submission	
Title	
Telephone	
Email	
Signature	
Date	

Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

For the purposes of describing the data at sections 1194(e)(1), 1194(e)(2), and 1193(a)(4)(A) of the Act to be collected for use in the Negotiation Program, as described in sections 40.2, 50.1, and 50.2 of this revised guidance and the Negotiation Data Elements Information Collection Request (ICR), CMS adopts the following definitions and standards.

General

- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment. If a Primary Manufacturer uses a cost of capital below 8.1 percent, that amount should be used.

Non-FAMP

- Non-FAMP: Section 1194(c)(6) of the Act defines "average non-Federal average manufacturer price" as the average of the non-FAMP (as defined in section 8126(h)(5) of title 38 of the U.S. Code) for the four calendar quarters of the year involved.[81] For initial price applicability year 2026, these are the quarters of 2021. When there are less than 30 days of commercial sales data for all NDC-11s of the selected drug in calendar year 2021, the applicable year will be the first full calendar year following market entry of such drug. When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) for a given NDC-11 of such drug, the non-FAMP reported by the manufacturer to CMS should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2023 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585. Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS.
- Non-FAMP unit: Non-FAMP unit is the package unit as described in 38 U.S.C. § 8126(h)(6).
- Non-FAMP dosage form unit: The non-FAMP dosage form unit is the dosage form of the NDC that is reported in the "Dose form" field of the Excel workbook used by the Office of Pharmacy Benefits Management Services at the VA to collect non-FAMP information.

Research and Development (R&D) Costs

R&D costs mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications of a drug falling into the five categories below, and excluding (a) prior Federal financial support, (b) costs associated with applying for and receiving foreign approvals,

[81] The term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account— (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount. 38 U.S.C. § 8126(h)(5).

and (c) costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Acquisition Costs
2. R&D: Basic Pre-Clinical Research Costs
3. R&D: Post-Investigational New Drug (IND) Application Costs
4. R&D: Abandoned and Failed Drug Costs
5. R&D: All Other R&D Direct Costs

CMS is calculating recoupment of R&D costs using both the global and U.S. total lifetime net revenue for the selected drug:

6. Recoupment: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

The definitions and associated time periods for these terms are included below.

Definitions for 1. R&D: Acquisition Costs

- For the sole purpose of data collection under section 1194(e)(1)(A) of the Act, acquisition costs are defined as costs associated with the Primary Manufacturer's purchase from another entity of the rights to hold previously approved or future NDA(s) / BLA(s) of the selected drug.

Definitions for 2. R&D: Basic Pre-Clinical Research Costs

- Basic pre-clinical research costs are defined as all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses (defined below).
- For each indication of the selected drug, the basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) to the day before the last IND application for that indication of the selected drug went into effect.[82, 83] The basic pre-clinical research period may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications that went into effect, use the date of the first IND application that went into effect as the end date for the 52-month period.[84]

[82] CMS acknowledges that the exact date of initial discovery might not be known, but manufacturers should use their best estimate.

[83] For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug, use the earliest date of acquisition for any NDA / BLA of the selected drug.

[84] CMS believes that 52 months represents a solid average across studies. For example, one study reported that the pre-clinical phase takes 52 months on average. See DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 2003, https://fds.duke.edu/db?attachment-

- Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect basic pre-clinical research costs and relevant general and administrative costs are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[85, 86] For example, if the *direct* pre-clinical research costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then *indirect* costs should be allocated proportionally, thus for the selected drug they should be 10 percent of the total spending on *indirect* pre-clinical research costs during that time period.

Definitions for 3. R&D: Post-Investigational New Drug (IND) Application Costs

- Post-IND costs are defined as all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication. Post-IND costs also include all direct costs associated with completed FDA-required, post-marketing trials that are conducted after the FDA has approved a product. Post-IND costs exclude FDA-required, post-marketing trials that were not completed.
- Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period. Direct post-IND costs also include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed FDA-required, post-marketing trial.

25--1301-view-168. Another study estimated that the pre-clinical phase can take 31 months on average. See DiMasi, J, Grabowski, H, Hansen, R. Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, 2016, as cited by the Congressional Budget Office (CBO) in Research and Development in the Pharmaceutical Industry, April 2021, https://www.cbo.gov/publication/57126. Other estimates have found that the pre-clinical phase ranges from three to six years. See PhRMA, "Biopharmaceutical Research & Development: The Process Behind New Medicines," 2015, http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

[85] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA.* 2020;323(9):844–853. doi:10.1001/jama.2020.1166

[86] Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html.

- The post-IND period begins on the day the IND went into effect for the first FDA-approved indication for the selected drug through the date when the last FDA-required post-marketing trial was completed for the selected drug.

Definitions for 4. R&D: Abandoned and Failed Drug Costs

- Failed or abandoned product costs include a sum of the portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
- Failed or abandoned product costs include a portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials.
    - Direct research expenses are costs that can specifically be attributed to the discovery and pre-clinical development of the drug.
    - Direct research expenses include personnel (compensation for investigators and staff) researching the drug, materials for conducting basic pre-clinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned product costs include a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
    - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
    - Direct post-IND costs include IRB review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting dosing and clinical trials for the drug.

Definitions for 5. R&D: All Other R&D Direct Costs

- All other R&D direct costs are any other allowable costs that do not align with R&D definitions 1-4. For example, other R&D direct costs may include direct costs associated with conducting FDA-required post-marketing trials that were not completed. No additional definitions adopted.

Definitions for 6. Global and U.S. Total Lifetime Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer's global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.

Definitions for 6a. Global, including U.S., Total Lifetime Net Revenue for the Selected Drug

- Global, total lifetime net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

- Global, total lifetime net revenue period is defined as the date the drug or biologic was first sold anywhere globally through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Definitions for 6b. U.S. Lifetime Net Revenue for the Selected Drug

- U.S. lifetime net revenue for the selected drug is defined as the direct sales and payments from U.S. entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
- U.S. lifetime net revenue period is defined as the date the drug or biologic was first sold in the U.S. through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If U.S. lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Current Unit Costs of Production and Distribution

- In accordance with section 1191(c)(6) of the Act, the term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)[87]: each (EA), milliliter (ML), or gram (GM). The unit reported must be specified for each of the NDC-11s of the selected drug. Selections of EA, ML or GM must be made as follows:
    - "EA" is used when the product is dispensed in discrete units. These products are not measured by volume or weight. The Billing Unit of "EA" is also used to address exceptions where "GM" and "ML" are not applicable. Examples of products defined as "EA" include, but are not limited to:
        - Tablets;
        - Capsules;
        - Suppositories;
        - Transdermal patches;
        - Non-filled syringes;
        - Tapes;
        - Devices/Digital Therapies;

[87] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

        - Blister packs;
        - Oral powder packets;
        - Powder filled vials for injection;
        - Kits;[88] and
        - Unit-of-use packages of products other than injectables with a quantity less than one milliliter or gram should be billed as "one each," for example, ointment in packets of less than 1 gram or eye drops in dropperettes that contain less than 1 ML.
    - "ML" is used when a product is measured by its liquid volume. Examples of products defined as "ML" include, but are not limited to:
        - Liquid non-injectable products of 1 ML or greater;
        - Liquid injectable products in vials/ampules/syringes;
        - Reconstitutable non-injectable products at the final volume after reconstitution except when they are in powder packets; and
        - Inhalers (when labeled as milliliters on the product).
    - "GM" is used when a product is measured by its weight. Examples of products defined as "GM" include, but are not limited to:
        - Creams (of 1 GM or greater);
        - Ointments (of 1 GM or greater); and
        - Inhalers (when labeled as GM on the product).[89]
- Costs of <u>production</u> are defined as all (direct and allocation of indirect) costs related to:
    - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
    - Formulation and preparation of the finished drug product;
    - Quality control and testing of the drug; and
    - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug.
- Costs of <u>distribution</u> are defined as all (direct and allocation of indirect) costs related to:
    - Packaging and packaging materials;
    - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
    - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
    - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- Current unit costs of production and distribution of the selected drug are defined to include:

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[88] Kits are defined as products that contain one of the following: (1) at least two distinct items with different billing units; (2) one product packaged with medicated or unmedicated swabs, wipes and/or cotton swabs/balls; or (3) meters packaged with test strips.

[89] See: https://standards.ncpdp.org/Standards/media/pdf/BUS_fact_sheet.pdf. *Permission is hereby granted to any organization to copy and distribute this material as long as this copyright statement is included, the contents are not changed, and the copies are not sold.*

  - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
  - Average unit costs during the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year);
  - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
  - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third parties (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
  - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug are defined not to include:
  - R&D costs; and
  - Marketing costs.
- "Marketing costs" are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, and other paid promotion.

Prior Federal Financial Support

For the purposes of describing prior federal financial support for novel therapeutic discovery and development to be collected for use in the Negotiation Program with respect to the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this revised guidance, CMS adopts the definitions described in this subsection.

- "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug.
- "*Prior* Federal financial support" refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, whichever is later, to the day through the date the most recent NDA / BLA was approved for the selected drug.

Patents, Exclusivities, and Approvals

- CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:
  - All patents issued by the United States Patent and Trademark Office (USPTO), as of September 1, 2023, both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected

drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
    - All patents related to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
    - All patent applications related to the selected drug that are pending issuance by the USPTO.
    - Patents and patent applications related to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book[90]; utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug; and design patents that, for example, claim a design on the packaging of the selected drug.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays and prohibitions on the approval of competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[91]
    - New Chemical Entity Exclusivity (NCE);[92]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[93]
    - New Clinical Investigation Exclusivity (NCI);[94]
    - Pediatric Exclusivity (PED);[95] and
    - Reference Product Exclusivity for Biological Products.[96]
- Active and pending FDA applications and approvals includes all applications for approval under section 505(c) of the FD&C Act or sections 351(a) of the PHS Act, including those not yet decided.

Market Data and Revenue and Sales Volume Data

- Wholesale Acquisition Cost (WAC) unit price: The manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC-11 level.

[90] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.
[91] Section 527 of the Federal Food, Drug and Cosmetic (FD&C) Act.
[92] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[93] Section 505E(a) of the FD&C Act.
[94] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[95] Section 505A(b) & (c) of the FD&C Act.
[96] Section 351(k)(7) of the PHS Act.

- National Council of Prescription Drug Programs (NCPDP) Billing Unit Standards: The three NCPDP Billing Unit Standards (BUS)[97] are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Medicaid best price: The Medicaid best price is defined in 42 C.F.R. § 447.505(a). The Medicaid best price is reported at the NDC-9 level.
- Average manufacturer price (AMP) unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Federal supply schedule (FSS) price: The price offered by the VA in its FSS program, by delegated authority of the General Services Administration.[98] The FSS price is reported at the NDC-11 level.
- Big Four price: The Big Four price is described in 38 U.S.C. § 8126. The Big Four price is reported at the NDC-11 level.
- U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price is reported at the NDC-11 level.
- U.S. commercial average net unit price─ without patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price net of manufacturer-run patient assistance programs that provide financial assistance such as coupons and co-payment assistance or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price─ without patient assistance program is reported at the NDC-11 level.
- U.S. commercial average net unit price─ best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any

[97] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.
[98] See: https://www.fss.va.gov/index.asp.

Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price─ best is reported at the NDC-11 level.

Evidence About Alternative Treatments

- Therapeutic Alternative: A therapeutic alternative must be a pharmaceutical product that is clinically comparable to the selected drug. CMS will consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off-label to treat a given indication. CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on the subset of therapeutic alternatives that are most clinically comparable to the selected drug.
- Outcomes: Outcomes may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life. Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients, and patient-reported outcomes will also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered, including patient-centered outcomes when available, to the extent that these outcomes correspond with a direct impact on individuals taking the drug. The caregiver perspective will be considered when there is a direct impact on the individuals taking the selected drug or therapeutic alternative.
- Patient-centered outcome: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves.[99]
- Specific populations: Specific populations include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries including those that may experience disparities in access to care, health outcomes, or other factors when taking the selected drug that impact health equity.
- Health equity: The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[100]
- Unmet medical need: A drug or biological product may be considered to meet an unmet medical need if the drug or biological product treats a disease or condition in cases where no other treatment options exist or existing treatments do not adequately address the

[99] Source: ISPOR Plenary, Patrick (2013) via FDA's "Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders" (June 2020). See: https://www.fda.gov/media/139088/download.
[100] See: https://www.cms.gov/pillar/health-equity.

disease or condition.[101] Unmet medical need is determined at the time of submission of this information.

[101] CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" (May 2014) when considering if a drug addresses an unmet medical need for the purpose of the Negotiation Program.

EXHIBIT B

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
(hereinafter referred to as the "Agreement")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act ("the Act"), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program"), which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as "maximum fair price" in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on [Date]; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the

Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section 1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—
   i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and
   ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.

b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—
   i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and
   ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.

c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—
   i. maximum fair price eligible individuals, who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and
   ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.

d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price

applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;
ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and
iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.

e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.
f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—
   i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and
   ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.
g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.
b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.
c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.

b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.
c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.
d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.
e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.
f) In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.
g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.
h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.
i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations, or guidance.
j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement.
k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 1: Negotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
NEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program; and

WHEREAS, the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug in accordance with the negotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a price for the Selected Drug, as published by CMS in accordance with section 1195(a) of the Act and updated in accordance with sections 1195(b) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement;

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.

b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.

c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth

in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing below, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____ _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 2: Renegotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
RENEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program and agreed to such a price on [Date(s)]; and

WHEREAS, the Manufacturer and CMS have engaged in renegotiation of the price for the Selected Drug in accordance with the renegotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a renegotiated price for the Selected Drug, as published by CMS in accordance with section 1194(f)(4) of the Act and updated in accordance with sections 1194(f)(4) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement; and

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.
b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.
c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing this, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____ _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____

EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: March 15, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

10. Introduction

The purpose of this memorandum is to provide interested parties with initial guidance regarding implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA) (P.L. 117-169), signed into law on August 16, 2022, which establish the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") to negotiate maximum fair prices (MFPs)[1] for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter "the Act") as added by sections 11001 and 11002 of the IRA.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this initial guidance for implementation of the Negotiation Program for initial price applicability year 2026. CMS is also voluntarily soliciting comment on certain topics in this memorandum where noted.[2] Please send comments pertaining to this memorandum to IRARebateandNegotiation@cms.hhs.gov with the following subject line "Medicare Drug Price Negotiation Program Guidance." Comments received by April 14, 2023

[1] In accordance with section 1191(c)(3) of the Social Security Act, ("the Act"), maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

[2] Because the Treasury Department and the Internal Revenue Service (IRS) anticipate issuing guidance separate from this document regarding the administration of the excise tax, CMS is not soliciting comment on section 90.3.

will be considered. CMS will issue revised guidance for initial price applicability year 2026 after considering the public comments received in response to this initial guidance.

In order to facilitate the timely implementation of the Negotiation Program, CMS is issuing guidance on section 30 of this memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception Information Collection Request (ICR) for which comments should be made in response to the ICR, as discussed in section 30.2.1 of this memorandum). This guidance is not subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute, due to the Congressional direction in section 11001(c) of the IRA to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. Moreover, to the extent that this guidance establishes or changes any substantive legal standard, CMS finds that notice and public procedure on this guidance would be impracticable, unnecessary, and contrary to the public interest, in light of this Congressional direction and in light of the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by September 1, 2023. There is accordingly good cause to issue those parts of this guidance that are final (i.e., section 30), without public comment and without a delayed effective date. 5 U.S.C. § 553(b)(B) & (d)(3); *see also* section 1871(b)(2)(C) of the Act.

In the revised guidance, CMS may make changes to any policies, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issues.

This initial guidance describes how CMS intends to implement the Negotiation Program for initial price applicability year 2026 (January 1, 2026 to December 31, 2026), and specifies the requirements that will be applicable to manufacturers of Medicare Part D drugs that are selected for negotiation and the procedures that may be applicable to manufacturers of Medicare Part D drugs, Medicare Part D plans (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs)), and providers and suppliers (including retail pharmacies) that furnish Medicare Part D drugs.

The table of contents for this memorandum is as follows:

- Section 10 – Introduction
- Section 20 – Overview
- Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2026
    - 30.1 Identification of Qualifying Single Source Part D Drugs for Initial Price Applicability Year 2026
        - 30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs
        - 30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs
        - 30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs
    - 30.2 Identification of Negotiation-Eligible Part D Drugs for Initial Price Applicability Year 2026
        - 30.2.1 Exception for Small Biotech Drugs

- 30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026
  - 30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry
    - 30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026
    - 30.3.1.2 High Likelihood
    - 30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026
    - 30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026
- 30.4 Publication of the Selected Drug List

- Section 40 – Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026
  - 40.1 Entrance into an Agreement with CMS
  - 40.2 Submission of Data to Inform Negotiation
    - 40.2.1 Confidentiality of Proprietary Information
    - 40.2.2 Data Use Provisions and Limitations
  - 40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years
  - 40.4 Providing Access to the MFP
    - 40.4.1 Nonduplication with 340B Ceiling Price
  - 40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program
  - 40.6. Termination of the Agreement
  - 40.7 Other Provisions in the Agreement
- Section 50 – Negotiation Factors
  - 50.1 Manufacturer-Specific Data
    - 50.1.1 Non-FAMP Data
  - 50.2 Evidence About Therapeutic Alternatives for the Selected Drug
- Section 60 – Negotiation Process
  - 60.1 Establishment of a Single Proposed MFP for Negotiation Purposes
  - 60.2 Limitations on Offer Amount
    - 60.2.1 Determination of the Ceiling for the MFP
    - 60.2.2 Sum of Plan Specific Enrollment Weighted Amounts
    - 60.2.3 Average Non-Federal Average Manufacturer Price
    - 60.2.4 Selection and Application of the Ceiling for the MFP
  - 60.3 Methodology for Developing an Initial Offer
    - 60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication
    - 60.3.2 Developing a Starting Point for the Initial Offer
    - 60.3.3 Adjusting the Starting Point Based on Clinical Benefit
      - 60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)
      - 60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives
    - 60.3.4 Consideration of Manufacturer-Specific Data
  - 60.4 Negotiation Process

        - 60.4.1 Provision of an Initial Offer and Justification
        - 60.4.2 Required Components of a Counteroffer
        - 60.4.3 Negotiation Process After Manufacturer Counteroffer
        - 60.4.4 Determination that Negotiations Have Finished
    - 60.5 Application of the MFP Across Dosage Forms and Strengths
        - 60.5.1 Application of the MFP to New NDAs/BLAs or NDCs
    - 60.6 Publication of the MFP
        - 60.6.1 Explanation for the MFP
    - 60.7 Exclusion from the Negotiation Process
    - 60.8 Establishment of MFPs After the Negotiation Deadline
- Section 70 – Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect
- Section 80 – MFP Eligible Individuals
- Section 90 – Manufacturer Compliance and Oversight
    - 90.1 Monitoring of Manufacturer Compliance
    - 90.2 Monitoring of Access to the MFP
    - 90.3 26 USC Section 5000D Excise Tax on Sale of Designated Drugs During Noncompliance Periods
    - 90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product
- Section 100 – Civil Monetary Penalties
    - 100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP
    - 100.2 Violations of the Agreement
    - 100.3 Provision of False Information
    - 100.4 Notice and Payment Procedures
- Section 110 – Part D Formulary Inclusion of Selected Drugs
- Section 120 – Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs
- Appendix A – Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026
- Appendix B – Template for the Initial Delay Request Form
- Appendix C – Definitions for Purposes of Collecting Manufacturer-Specific Data

20. Overview

In accordance with sections 11001 and 11002 of the IRA, which created Part E under Title XI of the Act (sections 1191 through 1198), the Secretary of the Department of Health and Human Services is required to establish the Negotiation Program to negotiate MFPs for certain high expenditure, single source Medicare drugs. With respect to each initial price applicability year, CMS shall (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate and, if applicable, renegotiate MFPs for such selected drugs, in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) enforce civil monetary penalties (CMPs) in accordance

with section 1197 of the Act. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

As noted above, in order to facilitate the timely implementation of the Negotiation Program, CMS is issuing guidance in section 30 of this memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception ICR, as discussed in section 30.2.1 of this memorandum). To allow for public input, CMS is voluntarily soliciting comments on all other sections except for section 90.3 (which states that the Treasury Department and the IRS anticipate issuing separate guidance on the administration of the excise tax), and specifically on certain topics in this memorandum, including:

- Terms and conditions contained in the manufacturer agreement, including the manufacturer's and CMS' responsibilities (included in section 40 of this memorandum);
- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments (included in section 60 of this memorandum);
- Process for the offer and counteroffer exchange between CMS and manufacturers (included in section 60 of this memorandum);
- Content of an explanation for the MFP (included in section 60 of this memorandum);
- Method for applying the MFP across different dosage forms and strengths of a selected drug (included in section 60 of this memorandum);
- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198 (included in section 60 of this memorandum); and
- Processes for compliance monitoring and imposition of CMPs for violations (included in section 90 of this memorandum).

More specific comment solicitations are included in certain sections of the memorandum. Topics that are not relevant to the Negotiation Program for initial price applicability year 2026, such as the selection of Medicare Part B drugs and renegotiation, will not be addressed in the guidance issued by CMS for initial price applicability year 2026. CMS will provide additional information in the future related to implementation for initial price applicability years 2027 and beyond.

30. Identification of Selected Drugs for Initial Price Applicability Year 2026

In order to facilitate the timely implementation of the Negotiation Program in accordance with statutory deadlines, CMS is issuing the guidance in this section 30 as final, without a comment solicitation (with the exception of the Small Biotech Exception ICR, as discussed in section 30.2.1 of this memorandum).

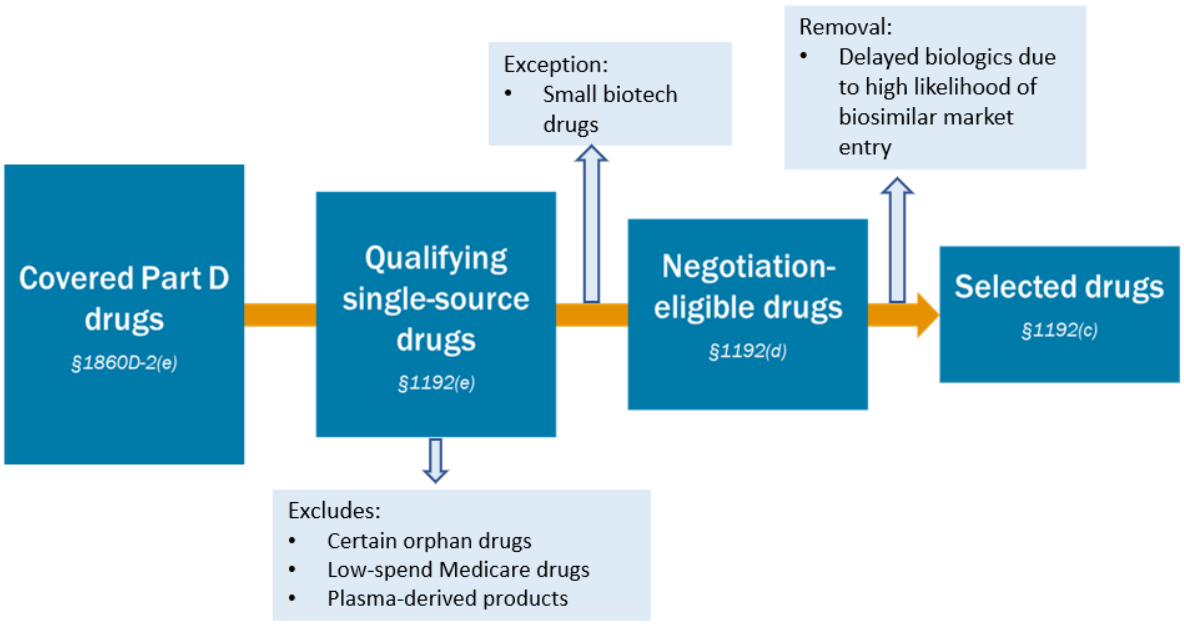
Section 1192 of the Act establishes the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs for an initial price applicability year. First, CMS will identify qualifying single source drugs in accordance with section 1192(e) of the Act, as described in section 30.1 of this memorandum. CMS will exclude certain drugs as required under the law. Next, in accordance with section

1192(d) of the Act, using Total Expenditures[3] under Part D of Title XVIII for these qualifying single source drugs calculated using Part D prescription drug event (PDE) data for dates of service between June 1, 2022, and May 31, 2023, and other information described below, CMS will identify negotiation-eligible drugs for initial price applicability year 2026 as described in section 30.2 of this memorandum (in this step, CMS will also exclude certain drugs as required under the law).

In accordance with section 1192(d)(1) of the Act, CMS will rank negotiation-eligible drugs for initial price applicability year 2026 according to the Total Expenditures for such drugs under Part D of Title XVIII for the 12-month period described above (detailed in section 30.3 of this memorandum). In accordance with section 1192(a) of the Act and subject to the Special Rule to delay the selection and negotiation of biologics for biosimilar market entry described in section 1192(f) of the Act, CMS will select the 10 negotiation-eligible Part D drugs with the highest Total Expenditures under Part D of Title XVIII for negotiation for initial price applicability year 2026 (described in section 30.3 of this memorandum) and publish a list of those ten selected drugs not later than September 1, 2023 (described in section 30.4 of this memorandum). Figure 1 provides a visual depiction of this process, and detailed guidance pertaining to this process for initial price applicability year 2026 is included below.

[3] For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3)). The term gross covered prescription drug costs is also defined in the Part D regulations at 42 CFR § 423.308. CMS has proposed to update this regulatory definition of gross covered prescription drug costs to eliminate any potential ambiguity in the regulation text and help to ensure there is a consistent understanding of the term for purposes of both the Part D program and the IRA. (See 87 FR 79611 through 79613, Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule).

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2026



30.1 Identification of Qualifying Single Source Part D Drugs for Initial Price Applicability Year 2026

In accordance with section 1192(e)(1) of the Act, CMS will define a qualifying single source Part D drug as a covered Part D drug (as defined in section 1860D-2(e) of the Act) that meets the following criteria:

- For drug products, a qualifying single source drug is a drug (1) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the date of such approval; and (3) that is not the listed drug for any drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act.
- For biological products, a qualifying single source drug is a biological product (1) that is licensed under section 351(a) of the Public Health Service Act (PHS Act) and marketed pursuant to such licensure; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 11 years have elapsed since the date of such licensure; and (3) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act.

Section 1192(d)(3)(B) of the Act states that CMS shall use data that are aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or

package type of the drug for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug under section 1192(d)(1) of the Act and applying the exception for small biotech drugs under section 1192(d)(2) of the Act.

Identifying potential qualifying single source drugs:
In accordance with the statutory language cited above, for purposes of the Negotiation Program, CMS will identify a potential qualifying single source drug using:

- For drug products, all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA)[4], inclusive of products that are marketed pursuant to different NDAs. The potential qualifying single source drug will also include all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such NDA(s), (2) authorized generic drugs that are marketed pursuant to such NDA(s), and (3) multi-market approval (MMA) products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s);
- For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA)[5], inclusive of products that are marketed pursuant to different BLAs. The potential qualifying single source drug will also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such BLA(s), (2) authorized biologic products that are marketed pursuant to such BLA(s), and (3) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such BLA(s).

As an example, entity A holds three NDAs for drug products with the same active moiety approved in NDA-1, NDA-2, and NDA-3. Entity A manufactures and markets three different strengths as an immediate release tablet pursuant to NDA-1, three different strengths as an extended release tablet pursuant to NDA-2, and three different strengths as a subcutaneous injectable pursuant to NDA-3. Additionally, entity B repackages three strengths of the immediate release tablets manufactured by entity A and markets them pursuant to NDA-1. In this scenario, all 12 of these drug products, including the repackaged products, will be aggregated as a single potential qualifying single source drug for purposes of identifying negotiation-eligible drugs.

This approach to identifying a potential qualifying single source drug aligns with the requirement in section 1192(d)(3)(B) of the Act to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. Consistent with this statutory instruction, this approach is also appropriate because the agency is aware that new dosage forms or different routes of administration of the same active moiety / active ingredient have been submitted by the same NDA/BLA holder and approved under different NDAs or BLAs.

[4] As described in section 505(c) of the FD&C Act.
[5] As described in 351(a) of the PHS Act.

Section 1192(e)(2)(A) of the Act states that an authorized generic drug and the qualifying single source drug that is the listed drug or reference product of that authorized generic drug shall be treated as the same qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act as (1) in the case of a drug product, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act), and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act[6] and is marketed, sold, or distributed, directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trade mark.

If a drug is a fixed combination drug[7] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying qualifying single-source drugs. Therefore, all formulations of this distinct combination offered by the same NDA/BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties / active ingredients that is offered by the same NDA/BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. For example, a long acting corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA/BLA holder that contains the same corticosteroid combined with a long acting beta agonist. In this example, the long acting corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

Applying statutory criteria for qualifying single source drugs:
In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, at least 7 years (for drug products) or 11 years (for biological products) must have elapsed between the U.S. Food and Drug Administration (FDA) date of approval or licensure, as applicable, and the selected drug publication date. To determine the date of approval or licensure for a potential qualifying single source drug with more than one FDA application number, CMS intends to use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA/BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients. The selected drug publication date for initial price applicability year 2026 is September 1, 2023, as specified in section 1191(d)(1) of the Act. As such, for initial price applicability year 2026, the initial approval for a drug product to be considered a qualifying single source drug must have been on or before September 1, 2016, and the date of initial licensure for a biological product to be considered a qualifying single source drug must have been on or before September 1, 2012.

[6] CMS is interpreting the reference to "licensed under section 351(a) of such Act" to mean licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.
[7] For purposes of the Negotiation Program, the term "fixed combination drug" has the meaning specified in 21 CFR 300.50.

For example, if 12 years had elapsed between the original approval for NDA-1 cited in the previous example above and September 1, 2023, then the potential qualifying single source drug defined above would meet this statutory criterion for qualifying single source drugs (even if less than seven years had elapsed between the approval dates for NDA-2 or NDA-3 and September 1, 2023).

In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, a product cannot be the listed drug for any drug approved and marketed under an ANDA under section 505(j) of the FD&C Act, and a biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act. CMS will use FDA reference sources, including the Orange Book[8] and Purple Book[9], to determine whether a generic drug or biosimilar biological product has been approved or licensed for any of the strengths or dosage forms of the potential qualifying single source drugs for initial price applicability year 2026.

In accordance with section 1192(c) and (e) of the Act for the purpose of identifying qualifying single source drugs for initial price applicability year 2026, CMS will review PDE data for a given generic drug or biosimilar biological product during the 12-month period beginning August 16, 2022 and ending August 15, 2023, using PDE data available on August 16, 2023, and will consider a generic drug or biosimilar biological product to be marketed when that data reveal that the manufacturer of that drug or product has engaged in bona fide marketing of that drug or product. CMS has chosen this time period to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published on September 1, 2023 in accordance with section 1192(a) of the Act.

If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar biological products that CMS determines are approved and marketed based on the process described above, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026. CMS will monitor the manufacturers of generics or biosimilar biological products to ensure they are engaging in bona fide marketing of the generic or biosimilar biological product (see section 90.4 of this memorandum for details).

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(A) of the Act, CMS will exclude certain orphan drugs when identifying qualifying single source drugs, referred to as the orphan drug exclusion. Specifically, CMS will exclude a drug or biological product that is designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and that is approved for only an indication (or indications) for such disease or condition. To be considered for the orphan drug exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and (2) be approved by the FDA only

[8] https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm
[9] https://purplebooksearch.fda.gov/

for one or more indications within such designated rare disease or condition. In order to qualify for the orphan drug exclusion, all dosage forms and strengths and different formulations of the qualifying single source drug described in section 30.1 of this memorandum must meet the criteria for exclusion. CMS will use the FDA Orphan Drug Product designation database[10] and approvals on the FDA website[11] to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion. CMS will also consult with FDA as needed. CMS is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development.

30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(B) of the Act, CMS will also exclude low-spend Medicare drugs with less than $200,000,000 in combined expenditures under Medicare Parts B and D when identifying qualifying single source drugs. For initial price applicability year 2026, CMS will identify low-spend Medicare drugs as follows:

- CMS will identify Part D PDE data combined with Part B claims data for each potential qualifying single source drug for dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. To allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been submitted no later than 30 days after May 31, 2023, i.e., by June 30, 2023. To allow a reasonable amount of time for providers and suppliers to submit Part B claims, CMS will use Part B claims data for the dates of service described above that have been submitted no later than 30 days after May 31, 2023, i.e. by June 30, 2023.
- For each potential qualifying single source drug as described in section 30.1 of this memorandum, CMS will use the PDE data to calculate the Total Expenditures under Part D and CMS will use the Part B claims data to calculate the total allowed charges, inclusive of beneficiary cost sharing under Part B.
- CMS will exclude from the final list of qualifying single source drugs for initial price applicability year 2026 any drugs for which the sum of Total Expenditures under Part D and total allowed charges, inclusive of beneficiary cost sharing, under Part B are less than $200 million.

30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(C) of the Act, CMS will exclude plasma-derived products when identifying qualifying single source drugs as described in section 30.1 of this memorandum. For purposes of this exclusion, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling. CMS will refer to product information available on the FDA Approved Blood Products

[10] https://www.accessdata.fda.gov/scripts/opdlisting/oopd/
[11] Drugs at FDA: https://www.accessdata.fda.gov/scripts/cder/daf/

website[12] to identify approved blood products regulated as biological products and the FDA Online Label Repository[13] to verify if the product is derived from human whole blood or plasma. CMS will also consult with FDA as needed.

30.2 Identification of Negotiation-Eligible Part D Drugs for Initial Price Applicability Year 2026

In accordance with section 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2026 is a qualifying single source drug that is among the 50 qualifying single source drugs with the highest Total Expenditures under Part D. CMS will identify the negotiation-eligible drugs for initial price applicability year 2026 as follows:

- CMS will identify all covered Part D drugs that are qualifying single source drugs for initial price applicability year 2026 using the process described in section 30.1 of this memorandum. CMS will exclude any drugs that qualify for the exclusions listed in sections 30.1.1 – 30.1.3 of this memorandum.
- CMS will identify Part D PDE data for each qualifying single source drug for dates of service during the applicable 12-month period beginning June 1, 2022 and ending May 31, 2023. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been accepted no later than 30 days after May 31, 2023, i.e., by June 30, 2023.
- CMS will use this PDE data to calculate the Total Expenditures under Part D for each qualifying single source drug during the 12-month applicable period.
- CMS will (1) remove drugs that are subject to the exception for small biotech drugs, discussed in section 30.2.1 of this memorandum; (2) rank the remaining qualifying single source drugs by Total Expenditures under Part D during the applicable 12-month period; and (3) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part D during the applicable 12-month period.
- These 50 drugs will be considered negotiation-eligible drugs for initial price applicability year 2026.

When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part D, and such Total Expenditures are the 50th highest among qualifying single source drugs, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number with its active moiety(ies) / active ingredient(s), until CMS has identified 50 negotiation-eligible drugs. CMS believes that this approach would not be likely to alter which drugs are selected drugs because a maximum of 10 drugs will be selected for initial price applicability year 2026 (see section 30.3 of this memorandum for details).

30.2.1 Exception for Small Biotech Drugs

In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source

[12] https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products
[13] https://labels.fda.gov/

drug that meets the requirements for the exception for small biotech drugs ("the Small Biotech Exception"). The statute requires that CMS consider, for Part D drugs, Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures for the qualifying single source drug under Part D during 2021, and Total Expenditures under Part D for all covered Part D drugs for which the manufacturer that had a Coverage Gap Discount Program agreement (CGDP agreement) in effect under section 1860D-14A of the Act for the qualifying single source drug during 2021 also had a CGDP agreement in effect during 2021.[14] To identify and exclude such small biotech drugs, CMS will consider whether, for dates of services in calendar year 2021, the Total Expenditures under Part D for the qualifying single source drug (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the drug had a CGDP agreement in effect during 2021. The Total Expenditures used in this calculation will not include any expenditures for products of repackers and relabelers who had CGDP agreements for the qualifying single source drug during 2021 subject to the aggregation rule at section 1192(d)(2)(B)(i) of the Act discussed below.

For the purposes of the Small Biotech Exception for initial price applicability year 2026, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all entities that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 with the entity that had the CGDP agreement for the qualifying single source drug on that date. However, CMS does not have information about which entities were treated as a single employer under the applicable IRC provisions. Therefore, a manufacturer that seeks the Small Biotech Exception for its qualifying single source drug ("Submitting Manufacturer") must submit information to CMS about the company and its products in order for the drug to be considered for the exception. To the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the NDA(s)/BLA(s) for the qualifying single source drug may be the Submitting Manufacturer. CMS has made this decision to ensure that only the entity with which CMS would negotiate in the event that the qualifying single source drug is selected for negotiation, as described in section 40 of this memorandum, is able to seek the Small Biotech Exception.

On January 24, 2023, CMS released the Small Biotech Exception ICR (CMS-10844 / OMB 0938-NEW) to detail the specific data that CMS are requesting for purposes of implementing this exception. Comments on the Small Biotech Exception ICR may be submitted according to the directions listed in the 60-day notice that appeared in the Federal Register on January 24, 2023 (88 FR 4184).[15] Comments in response to the 60-day notice must be submitted by March 27, 2023. The public will have an additional opportunity to submit comments for 30 days following issuance of the 30-day Federal Register notice for this ICR.

[14] For the purposes of this determination, a manufacturer who participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's CGDP agreement would be considered to have had an agreement in effect during 2021.

[15] https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10844

The Small Biotech Exception ICR addresses the collection of information for initial price applicability year 2026 only. As, in accordance with section 1192(a)(3) of the Act, Part B drugs are not selected for negotiation until initial price applicability year 2028, this ICR does not address the collection of information relevant to Part B drugs. Additionally, this ICR does not address the collection of information relevant to the statutory limitation found in section 1192(d)(2)(B)(ii) of the Act (which precludes the application of the Small Biotech Exception to a qualifying single source drug if the manufacturer of that drug is acquired after 2021 by a manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii)) because the earliest effective date specified in that limitation (January 1, 2025) has no impact until initial price applicability year 2027 (the first initial price applicability year with a selected drug publication date after January 1, 2025).

To receive consideration for the Small Biotech Exception for initial price applicability year 2026, the Submitting Manufacturer must submit the Small Biotech Exception Information Collection Request Form using the CMS Health Plan Management System (HPMS) by the deadline established by CMS; CMS anticipates that this deadline will be in June 2023 but will publish a specific deadline on the CMS IRA website in the future.[16] This due date will be in advance of the date on which CMS is required to publish the list of selected drugs for initial price applicability year 2026 and will allow sufficient time for CMS to consider whether the qualifying single source drug qualifies for the Small Biotech Exception.

CMS does not plan to consider incomplete submissions. Upon receipt of a complete Small Biotech Exception Information Collection Request Form, CMS plans to take the following approach to identify whether a drug qualifies for the Small Biotech Exception:

- CMS plans to identify the manufacturer that had a CGDP agreement for the drug in effect as of December 31, 2021 ("2021 Manufacturer") based on the information submitted in the Small Biotech Exception Information Collection Request Form.
- CMS plans to use the identifying information (manufacturer name, P-number, and labeler codes) submitted in that form to identify the complete set of 11-digit National Drug Codes (NDC-11s)[17] for which any member of the 2021 Manufacturer's controlled group as of December 31, 2021 had a CGDP agreement as of December 31, 2021. "Controlled group" means all corporations or partnerships, proprietorships and other entities treated as a single employer under 26 U.S.C. § 52(a) or (b).
- Using the complete set of NDC-11s for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect on December 31, 2021, CMS plans to identify Part D PDE data for dates of service during the 12-month period beginning January 1, 2021 and ending December 31, 2021.
- Using the PDE data for (1) the qualifying single source drug, (2) the complete set of covered Part D drugs for which the 2021 Manufacturer or any member of the 2021

[16] https://www.cms.gov/inflation-reduction-act-and-medicare

[17] NDC-9 and NDC-11 numbers are identical except for two numbers in NDC-11s that indicate package size. Because of this, NDC-11 is more granular than NDC-9, and multiple NDC-11 numbers can aggregate under a single NDC-9 number.

Manufacturer's controlled group had a CGDP agreement as of December 31, 2021, and (3) all covered Part D drugs, CMS plans to determine whether:

- The Total Expenditures under Part D for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and
- The Total Expenditures under Part D for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect during 2021.

For initial price applicability year 2026, the term "negotiation-eligible drug" will exclude any covered Part D drugs that are qualifying single source drugs that meet these criteria to qualify for the Small Biotech Exception.

A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years. The Submitting Manufacturer must resubmit a request for the drug to be considered for the exception for initial price applicability years 2027 and 2028. The process for resubmitting a request will be addressed in future guidance.

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026

In accordance with sections 1192(a) and 1192(b) of the Act, CMS will select 10 (or all, if such number is less than 10) negotiation-eligible Part D drugs for initial price applicability year 2026 as follows:

- CMS will rank the 50 negotiation-eligible drugs identified in section 30.2 of this memorandum by Total Expenditures under Part D (based on the data described in section 30.2 of this memorandum) in descending order: the negotiation-eligible drug with the highest Total Expenditures under Part D will be listed first and the negotiation-eligible drug with the lowest Total Expenditures under Part D will be listed last.
- CMS will remove any biological products that qualify for delayed selection under section 1192(f) of the Act as described in section 30.3.1 of this memorandum.
- CMS will select for negotiation the 10 (or all, if such number is less than 10) highest ranked negotiation-eligible drugs remaining on the ranked list for initial price applicability year 2026.
    - In the event that two or more negotiation-eligible drugs have the same Total Expenditures to the dollar under Part D and such Total Expenditures are the 10th highest among negotiation-eligible drugs, CMS will rank those negotiation-eligible drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the initial FDA application number for its active moiety(ies) / active ingredient(s), and select based on that ranking until there are 10 selected drugs (or all drugs are selected if the number of negotiation-eligible drugs is less than 10).

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

In accordance with section 1192(b)(1)(C) of the Act, CMS will remove from the ranked list of 50 negotiation-eligible drugs described in section 30.3 of this memorandum any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. This section 30.3.1 describes the implementation of section 1192(f) of the Act (the "Biosimilar Delay").

Under section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by FDA. CMS believes that this approach is appropriate because (1) it clearly identifies one manufacturer who may submit a Biosimilar Delay request for a given Biosimilar, avoiding the possibility that CMS would receive two such requests naming the same Biosimilar for the same initial price applicability year, and (2) the status of the application for licensure for the Biosimilar is material to CMS' consideration of a Biosimilar Delay request, as described in this section 30.3.1.

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year ("Additional Delay Request") as stated in section 1192(f)(1)(B)(i)(II) of the Act.

The following subsections of this section 30.3.1 include details on the implementation of the Biosimilar Delay for initial price applicability year 2026. Topics related to future initial price applicability years (including Additional Delay Requests) will be covered in future guidance.

30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026

The statute specifies that the following requirements must be met in order for CMS to grant an Initial Delay Request:

1. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be, absent the Biosimilar Delay, a selected drug for the initial price applicability year.
    - Biosimilar Manufacturers who think that a Reference Drug for their Biosimilar may be a selected drug for initial price applicability year 2026 may submit an Initial Delay Request, and CMS will disregard that application if the Reference

Drug would not, in fact, be a selected drug for initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug.

2. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests submitted with respect to initial price applicability year 2026, this means that the Reference Drug must have received its initial BLA licensure between January 1, 2010, and January 1, 2014.
    - Section 1194(c)(4)(B)(ii) of the Act specifies that selected drugs for which a manufacturer had an agreement under the Negotiation Program for an initial price applicability year prior to 2030 are excluded from the definition of extended-monopoly drugs. Importantly, however, an Initial Delay Request must be submitted by a Biosimilar Manufacturer before the selected drug publication date for an initial price applicability year and before the Primary Manufacturer (as defined in section 40 of this memorandum) of the Reference Drug ("Reference Manufacturer") would have entered into an agreement under the Negotiation Program. Therefore, CMS believes the exception to the definition of "extended-monopoly drug" in section 1194(c)(4)(B)(ii) of the Act will not apply at the time that a delay would be requested for initial price applicability years 2026 through 2029. Accordingly, CMS believes that the Biosimilar Delay under section 1192(f) of the Act is applicable beginning with initial price applicability year 2026. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2026, provided that the Reference Drug named in the request will have been licensed for between 12 and 16 years prior to the start of the initial price applicability year on January 1, 2026.
3. In accordance with section 1192(f)(1)(A) of the Act, the Reference Drug must include the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by the FDA or accepted for review, as described below in section 30.3.1.2 of this memorandum.
    - Please note that in order for CMS to grant an Initial Delay Request, the licensure application for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval.
4. In accordance with section 1192(f)(2)(D)(iii) of the Act, an Initial Delay Request cannot be granted if more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
    - For Initial Delay Requests submitted with respect to initial price applicability year 2026, this requirement means that if the Biosimilar has already received approval by the FDA for its application for licensure under section 351(k) of the PHS Act, the date of such licensure must be on or after September 1, 2022 for a delay to be granted. If the Biosimilar is already licensed and marketed by September 1, 2023,

the selected drug publication date for initial price applicability year 2026, the Reference Drug would by definition no longer be a qualifying single source drug and therefore would fail requirement #1 on this list. If the Biosimilar was licensed prior to September 1, 2022 and is not marketed before September 1, 2023, more than one year would have elapsed since the licensure of the Biosimilar without marketing of the Biosimilar having commenced.

5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC of 1986, or in a partnership, shall be treated as one manufacturer, as stated in section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, "partnership" is defined at section 1192(f)(1)(C)(ii) of the Act as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer.
6. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that either:
    - requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
    - directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time. For Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after September 1, 2023 as violating this requirement.
7. In accordance with section 1192(f)(1)(A) of the Act and as described in detail in section 30.3.1.2 of this memorandum, CMS must determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year.

30.3.1.2 High Likelihood

In accordance with section 1192(f)(1)(A) of the Act, CMS will review Initial Delay Requests to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year. Accordingly, for Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS must find a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, in order to grant the request. If CMS does not find that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described below, CMS will deny the Initial Delay Request.

In accordance with section 1192(f)(3) of the Act, Initial Delay Requests must demonstrate both of the following in order meet the high likelihood threshold:

1. An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA.
    - For Initial Delay Requests submitted with respect to initial price applicability year 2026, the Biosimilar's application for licensure must be approved or accepted for review by the FDA no later than August 15, 2023, in order to permit CMS time to review the information and finalize the selected drug list prior to the selected drug publication date of September 1, 2023.
    - Please note that if the Biosimilar's application for licensure has not been accepted for review by August 15, 2023, including in the case where the Biosimilar Manufacturer has submitted an application for licensure that has not been accepted for review by the FDA or for which a filing determination is pending, CMS will deny the Initial Delay Request for initial price applicability year 2026.
2. Clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025 (the date that is two years after the selected drug publication date for the initial price applicability year), based on the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS.

For Initial Delay Requests submitted for initial price applicability year 2026, to demonstrate clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025, CMS will require that the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS by the Biosimilar Manufacturer as part of its Initial Delay Request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. CMS has chosen these two requirements because they represent the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date.

First, the Initial Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025. Specifically, CMS will consider this requirement met if (1) there are no non-expired approved patent applications relating to the Reference Drug that are applicable to the Biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable non-expired patent relating to the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar in one or more dosage form(s), strength(s), and indication(s) before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer.[18] CMS will deny

[18] As noted in section 30.3.1.1 of this memorandum, an Initial Delay Request will not be granted if the Biosimilar Manufacturer enters into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar

all Initial Delay Requests that do not meet this requirement including, for example, if the Biosimilar Manufacturer is engaged in active litigation with the Reference Manufacturer with respect to the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act. CMS will consider active litigation to be determinative that there is not clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025, because litigation, including patent litigation, is historically highly unpredictable with respect to both the outcome of the litigation and the timing for resolution.

Second, the Initial Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before September 1, 2025. To assess this requirement, CMS will consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before September 1, 2025, and (2) a manufacturing schedule consistent with the public-facing statements and any revenue expectations. CMS has chosen these criteria because they are indicative of operational readiness and should be available in the elements that CMS must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act.

In determining whether an Initial Delay Request satisfies the high likelihood threshold, CMS may use all the information outlined in section 30.3.1.3 of this memorandum to determine whether an application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA. In accordance with section 1192(f)(3)(B) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025:

- All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and
- Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies.

Manufacturer to submit an Initial Delay Request or directly or indirectly restricts the quantity of the Biosimilar sold in the United States on or after September 1, 2023.

In accordance with section 1198(2) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1192(f) of the Act.

30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026

A Biosimilar Manufacturer should submit an Initial Delay Request for initial price applicability year 2026 only if it (1) plans for its Biosimilar to be licensed and marketed before September 1, 2025, (2) believes its request will satisfy the statutory requirements for granting an Initial Delay Request, as described in section 30.3.1.1 of this memorandum, and (3) believes that its request demonstrates that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described in section 30.3.1.2 of this memorandum.[19]

CMS has designed the process for Initial Delay Request submission for initial price applicability year 2026 to allow CMS time to adjudicate all requests in advance of September 1, 2023, the selected drug publication date, and to be operationally feasible. For initial price applicability year 2026, CMS will accept Initial Delay Requests submitted via email and Box[20] as described below, whereas, for future initial price applicability years, CMS plans to issue guidance on use of the CMS HPMS to receive and process these requests in the future.

Accordingly, Initial Delay Requests for initial price applicability year 2026 may be submitted via the following process:

1. The Biosimilar Manufacturer should send an email to IRARebateandNegotiation@cms.hhs.gov to indicate its intention to submit an Initial Delay Request for initial price applicability year 2026. The Biosimilar Manufacturer is encouraged to use the template, including subject line and body content, described in Appendix A of this memorandum. Emails should be received by 11:59 pm PT on May 10, 2023.
2. Within 5 business days of receipt, CMS will respond by providing the Biosimilar Manufacturer with (1) a fillable template for the Initial Delay Request form, available in Appendix B of this memorandum, and (2) access to a Box folder specific to the Biosimilar Manufacturer's Initial Delay Request. No parties other than the Biosimilar Manufacturer and CMS and its contractors will have access to this folder.
3. The Biosimilar Manufacturer should upload a complete Initial Delay Request with the following documentation to the Box folder or using an alternative submission approach approved by CMS by 11:59 pm PT on May 22, 2023. CMS will deem an Initial Delay Request to be complete if it includes:

[19] For initial price applicability year 2026, an Initial Delay Request would be submitted by a Biosimilar Manufacturer that anticipates the reference product for its Biosimilar will be included in one of the ten covered Part D Drugs that will be a selected drug for this initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug.

[20] https://www.box.com/; if a Biosimilar Manufacturer is unable to use Box, it should include an explanation in its email in step #1 below and request an alternative submission method.

a. A complete Initial Delay Request form using the fillable template that the Biosimilar Manufacturer receives from CMS. This template can be used to submit:
    i. information used to identify the Biosimilar Manufacturer, the Biosimilar, the Biosimilar's reference product, and the Reference Manufacturer;
    ii. attestations that the Initial Delay Request meets the statutory requirements listed in section 30.3.1.1 of this memorandum; and
    iii. information on the status of licensure for the Biosimilar under section 351(k) of the PHS Act;
b. All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
c. The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
d. Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.

In accordance with section 1192(f)(1)(B)(ii) of the Act, Initial Delay Requests for initial price applicability year 2026 that are not submitted by 11:59 pm PT on May 22, 2023 or that do not include all elements will be denied.

30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026

Within 5 business days after the Biosimilar Manufacturer uploads the required documentation to its Box folder or using an alternative submission approach approved by CMS, CMS will send an email confirming receipt to the email address used by the Biosimilar Manufacturer in its initial email to CMS expressing its intent to submit an Initial Delay Request. In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Initial Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request. For initial price applicability year 2026, CMS will make any such follow-up request in writing to the Biosimilar Manufacturer via the same email address on or before June 20, 2023. Any such written request will specify the additional information required, the format and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information, which will be no later than July 3, 2023. The one exception to these

deadlines is as follows: per section 30.3.1.2 of this memorandum, for CMS to determine that there is a high likelihood of the Biosimilar being licensed and marketed prior to September 1, 2025, the Biosimilar's application for licensure must be accepted for review or approved by the FDA no later than August 15, 2023. CMS will permit the Biosimilar Manufacturer to update CMS on the status of the Biosimilar's application for licensure before 11:59 pm PT on August 15, 2023, in order to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published on September 1, 2023, in accordance with section 1192(a) of the Act.

Prior to September 1, 2023, the selected drug publication date for initial price applicability year 2026, CMS will review each Initial Delay Request in the following manner. First, CMS will review each Initial Delay Request to determine whether it includes all of the elements for an Initial Delay Request and was submitted by the applicable deadline in accordance with section 30.3.1.3 of this memorandum. Second, if an Initial Delay Request includes all required elements and was timely submitted, CMS will review the Initial Delay Request to determine if it meets all of the statutory requirements described in section 30.3.1.1 of this memorandum, with the exception of the high likelihood requirement. Third, if the Initial Delay Request meets all statutory requirements other than the high likelihood requirement, CMS will review the Initial Delay Request to determine whether it demonstrates a high likelihood that the Biosimilar will be licensed and marketed by September 1, 2025, as described in section 30.3.1.2 of this memorandum. In considering an Initial Delay Request, CMS will cease consideration upon finding that the Initial Delay Request has failed to meet any of these requirements. For example, if CMS determines an Initial Delay Request was not submitted by the established deadline, CMS will not review that request against other statutory requirements; if CMS determines an Initial Delay Request fails to meet one or more of the statutory requirements described in section 30.3.1.1 of this memorandum, with the exception of the high likelihood requirement, CMS will not consider whether that Initial Delay Request demonstrates a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

The list of selected drugs published for initial price applicability year 2026 will reflect the results of CMS' determinations with respect to any Initial Delay Requests that are submitted, i.e., a Reference Drug that, absent a successful Initial Delay Request, would have been selected, will not appear on the selected drug list published by September 1, 2023 if it is named in a successful Initial Delay Request.

After completing its review, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2026 in writing of CMS' determination regarding such request. This notification will occur on or after September 1, 2023, but no later than September 30, 2023, and will include a brief summary of CMS' determination, including:

- Whether the Initial Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined that the Initial Delay Request was unsuccessful, including but not limited to:
    - failure to submit all elements of the Initial Delay Request by the applicable deadline;

- failure to meet another statutory requirement for granting a request (other than the high likelihood requirement), including in the case that the Reference Drug would not have been a selected drug for initial price applicability year 2026 absent the Initial Delay Request; or
- failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

CMS will also notify each Reference Manufacturer named in a successful Initial Delay Request using the CMS HPMS to identify the relevant point(s) of contact. Such notification will be in writing and will identify the Reference Drug that would have been a selected drug in initial price applicability year 2026, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests will not be notified.

In accordance with section 1192(f)(2)(B) of the Act, CMS must determine whether each Biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period. For successful Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will make this determination by mid-2024 (note: CMS plans to publish a specific date in future guidance as this deadline remains over one year away and CMS is still determining the appropriate date by which this determination should be made). The timing, content, and format of this notification will be specified in future guidance.

The following table provides a summary of key dates specified in this section 30.3.1:

Date	**Deadline / milestone**
11:59 pm PT on May 10, 2023	Deadline for Biosimilar Manufacturer to email CMS regarding intent to submit Initial Delay Request for initial price applicability year 2026
11:59 pm PT on May 22, 2023	Deadline for Biosimilar Manufacturer to submit the documentation for its Initial Delay Request as specified in section 30.3.1.3 of this memorandum
June 20, 2023	Deadline for CMS to request follow-up information for a submitted Initial Delay Request, if applicable
July 3, 2023	Deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS, if applicable
11:59 pm PT on August 15, 2023	Deadline for Biosimilar application for licensure to be accepted for review or approved by the FDA; deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS related to the Biosimilar application for licensure
September 1, 2023	Statutory deadline for CMS to publish the selected drug list for initial price applicability year 2026
September, 2023	CMS informs each Biosimilar Manufacturer that submitted an Initial Delay Request of the results of such request, in writing; for successful Initial Delay Requests, CMS also informs the Reference Manufacturer
Mid-2024[21]	For successful Initial Delay Requests, CMS determines whether the Biosimilar has been licensed and marketed during the initial delay period

[21] CMS plans to publish a specific date in future guidance.

Information on other policies related to section 1192(f) of the Act will be included in future guidance, including, but not limited to:

- the deadline and process for submitting an Initial Delay Request for initial price applicability year 2027;
- the deadline and process for submitting an Additional Delay Request for initial price applicability year 2027, in the event an Initial Delay Request for initial price applicability year 2026 is granted and CMS determines by mid-2024 that the Biosimilar was not licensed and marketed during the initial delay period;[22]
- the criteria for adjudicating Additional Delay Requests;
- the impact of Initial Delay Requests and Additional Delay Requests on the selected drug list for initial price applicability year 2027; and
- the application and calculation of rebates for a Reference Drug for 2026, as applicable.

30.4. Publication of the Selected Drug List

In accordance with section 1192(a) of the Act, CMS will publish the selected drug list for initial price applicability year 2026 no later than September 1, 2023. This list will include the 10 (or all, if such number is less than 10) drugs selected for negotiation for initial price applicability year 2026. CMS will post the selected drug list on the CMS IRA webpage.[23]

40. Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026

In accordance with section 1193(a) of the Act, the Secretary shall enter into agreements with manufacturers of selected drugs. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS intends to designate the entity that holds the NDA(s)/BLA(s) for the selected drug to be "the manufacturer" of the selected drug (hereinafter "Primary Manufacturer"). Likewise, for initial price applicability year 2026, CMS intends to refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer as a "Secondary Manufacturer." Secondary Manufacturers would include any manufacturer of any authorized generics and any repacker or relabeler of the selected drug that meet these criteria.

In the example discussed in section 30.1 of this memorandum, if the potential qualifying single source drug described was selected for negotiation, entity A would be considered the Primary Manufacturer while entity B would be considered a Secondary Manufacturer either because it was listed as a manufacturer in NDA-1 or if it was not listed as a manufacturer in NDA-1

[22] CMS plans to publish a specific date in future guidance.
[23] https://www.cms.gov/inflation-reduction-act-and-medicare

because it markets the three strengths of the immediate release tablets manufactured by entity A pursuant to an agreement with entity A.

CMS intends to sign an agreement (a "Medicare Drug Price Negotiation Program Agreement," herein referred to as an "Agreement"), with the Primary Manufacturer of each selected drug and believes this approach aligns with the statute's requirement to negotiate to determine an MFP with "the manufacturer" of a selected drug in accordance with section 1193(a) of the Act. This Agreement, as described in this section 40, will contain the requirements of the Primary Manufacturer with respect to its participation in the Negotiation Program.

CMS does not intend to enter into an Agreement with any Secondary Manufacturer of a selected drug. As such, under section 1193(a)(4), CMS intends to include in the Agreement with the Primary Manufacturer several requirements pertaining to Secondary Manufacturers of the selected drug, as applicable, including that a Primary Manufacturer that enters into an Agreement must: (1) report to CMS a list of any Secondary Manufacturer(s) and the applicable NDC-11s of the selected drug marketed by each such Secondary Manufacturer(s); and (2) collect and report necessary information applicable to any Secondary Manufacturer(s) as described in section 40.2 of this memorandum. Further, in accordance with section 1193(a)(1) of the Act and section 40.4 of this memorandum, CMS intends to require that the Primary Manufacturer ensure that any Secondary Manufacturer(s) make the MFP available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers. CMS reiterates that the requirement to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as discussed in section 80 of this memorandum.

CMS intends that for initial price applicability year 2026, the Primary Manufacturer of a selected drug will be the entity that does each of the following:

1. Signs the Agreement with CMS, as described in section 40.1 of this memorandum;
2. Collects and reports all data required for negotiation under section 1193(a)(4) of the Act, including the negotiation data elements, as described in section 40.2, section 50.1, and Appendix C of this memorandum;
3. Negotiates an MFP with CMS, as described in section 40.3 of this memorandum;
4. Ensures the MFP is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that dispense the selected drug to those individuals, as described in section 40.4 of this memorandum; and
5. Responds to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities, and pays any CMPs for violations, including violating the terms of the Agreement, providing false information, failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but that has since undergone negotiation as described in section 1192(f)(4) of the Act, or not providing access to the MFP to MFP-eligible individuals, and to pharmacies, mail order services, and other dispensers, as described in section 40.5, section 90, and section 100 of this memorandum.

Termination of an Agreement for the Negotiation Program is discussed in section 40.6 of this memorandum and other relevant provisions from the Agreement are discussed in section 40.7. CMS is seeking comment on the policies described in this section 40 of this memorandum, including on other ways it might operationalize the statutory requirement to negotiate a single MFP with "the manufacturer" of a selected drug.

40.1 Entrance into an Agreement with CMS

Section 1193(a) of the Act instructs CMS to enter into agreements with manufacturers of selected drugs for a price applicability period. The deadline for the Primary Manufacturer of a selected drug to enter into an Agreement for initial price applicability year 2026 is October 1, 2023. CMS intends to use the CMS HPMS to identify the relevant points of contact, effectuate the Agreement, and store the Agreement.[24] Further, CMS intends for the Agreement to contain the requirements discussed in sections 40.1 through 40.7 of this memorandum.

Within 5 days following publication by CMS of the list of selected drugs for an initial price applicability year, if the Primary Manufacturer of a selected drug elects to enter into an Agreement with CMS to negotiate an MFP, the Primary Manufacturer must submit to CMS all names, titles, and contact information for representatives authorized to execute the Agreement and conduct the negotiation. This person or persons must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Agreement. At least one authorized representative of the Primary Manufacturer must access the CMS HPMS and sign the Agreement by October 1, 2023.

The negotiation period for initial price applicability year 2026 will begin on the earlier of two dates: the date on which the Agreement is executed (i.e., signed by both CMS and the Primary Manufacturer) or October 1, 2023. If an Agreement is fully executed before October 1, 2023, the negotiation period (as defined in 1191(b)(4) of the Act) would begin on the date on which the Agreement is signed by the last party to sign it. If the Agreement is not fully executed by October 1, 2023, then pursuant to 26 U.S.C. § 5000D(b)(1), a noncompliance period would begin on October 2, 2023, and could result in excise tax liability (see section 90.3 of this memorandum). CMS notes that entering into an Agreement is voluntary.

CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list for initial price applicability year 2026 is published.

40.2 Submission of Data to Inform Negotiation

After entering in an Agreement with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug must submit to CMS the following information with respect to the selected drug: information on the non-Federal average manufacturer price (defined in section 8126(h)(5) of title 38, United States Code) as described in section 50.1.1 of this memorandum; and any information that CMS requires to carry out negotiation, including the factors listed in section 1194(e)(1) of the Act, as described in section 50.1 and Appendix C of

[24] https://hpms.cms.gov/app/ng/home/

this memorandum. This information must be submitted by the Primary Manufacturer to CMS no later than October 2, 2023, for initial price applicability year 2026.

CMS intends to require that the Agreement be fully executed, meaning both the Primary Manufacturer and CMS have signed the Agreement, before the Primary Manufacturer may submit the data elements described in this section. While these data elements may not be submitted prior to execution of the Agreement, CMS intends for Primary Manufacturers to be able to access the data elements template in the CMS HPMS and believes Primary Manufacturers will be able to gather these data prior to the Agreement being executed.

Importantly, certain data, as described in section 50.1 and Appendix C of this memorandum, must reflect any products included in the selected drug marketed by a Secondary Manufacturer(s), as applicable, and the Primary Manufacturer is responsible for collecting such data from any Secondary Manufacturer(s) and including this information in its submission to CMS.

CMS intends to populate the CMS HPMS with a list of the approved and marketed NDC-11s used to calculate the Total Expenditures for each selected drug (see additional details in sections 30.2 and 30.3 of this memorandum). A Primary Manufacturer must either attest that the listed NDC-11s are correct and marketed by the Primary Manufacturer or any Secondary Manufacturer(s) and that no NDC-11s are incorrectly included or missing from the list or provide any corrections to CMS. CMS intends to collect this information in the CMS HPMS concurrent with the collection of the other data elements specified in section 50.1 of this memorandum. In order to ensure accuracy of payment systems, CMS intends to require a Primary Manufacturer to report to CMS in writing any new approved and marketed NDC-11s of the selected drug at least 30 days prior to their first marketed date for any Primary Manufacturer or Secondary Manufacturer. CMS also intends to require the Primary Manufacturer to report to CMS in writing the delisting of any NDC-11 of the selected drug that is no longer marketed by the Primary Manufacturer or any Secondary Manufacturer(s) within 30 days after its discontinuation.

CMS is seeking comment on this section. Specifically, CMS is seeking comment on the requirement that Primary Manufacturers submit data under section 1193(a)(4) of the Act, including the factors listed in section 1194(e)(1) of the Act, for the Primary Manufacturer and any Secondary Manufacturer(s). CMS is also seeking comment on the requirement for Primary Manufacturers to report to CMS any new approved and marketed NDC-11s, or discontinued NDC-11s, of the selected drug for the Primary Manufacturer and on behalf of any Secondary Manufacturer(s).

40.2.1 Confidentiality of Proprietary Information

Section 1193(c) of the Act states that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secret and confidential commercial or financial

information, would also be protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(4)).[25]

CMS intends to implement a confidentiality policy that is consistent with existing requirements for protecting proprietary information, such as Exemption 4 of FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary.

Thus, for initial price applicability year 2026, CMS intends to treat information on non-Federal average manufacturer price ("non-FAMP") (as defined in section 8126(h)(5) of title 38 of the U.S. Code) as proprietary.

For initial price applicability year 2026, CMS also intends to treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) of the Act as proprietary if the information constitutes commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that cannot be found publicly. Specifically, CMS intends to treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, and market data and revenue and sales volume data to be proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS intends to treat the data on prior Federal funding and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS believes these data are available publicly.

Pursuant to section 1195(a)(2) of the Act, CMS is required to publish the explanation for the MFP by March 1, 2025 for initial price applicability year 2026 (see section 60.6.1 of this memorandum). In this public explanation and any other public documents discussing the MFP, CMS intends to make high-level comments about the data submitted to CMS, without sharing any proprietary information reported to CMS under section 1193(a)(4) for purposes of the negotiation. For example, CMS does not intend to make public the research and development costs reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may say "the manufacturer has recouped its research and development costs."

With respect to information disclosed under the terms of the Agreement, CMS intends for the confidentiality provisions of the Agreement to survive termination of the Agreement.

CMS is seeking comment on the confidentiality policy described in this section 40.2.1. Specifically, CMS is seeking comment on which manufacturer data elements require submission of proprietary information and the basis for such conclusion. CMS is also requesting comment on the type of information that would not be considered proprietary and that CMS could include in the public explanation of MFP. In addition, CMS is seeking comment about the proper

[25] https://www.justice.gov/archives/oip/foia-guide-2004-edition-exemption-4#:~:text=Exemption%204%20of%20the%20FOIA,government%20and%20submitters%20of%20information

balance between the public's interests in transparency and the protection of business information in this context.

40.2.2 Data Use Provisions and Limitations

Under section 1193(a)(5) of the Act, the manufacturer of a selected drug must comply with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program. Pursuant to this authority, CMS intends to impose certain requirements on the Primary Manufacturer related to the submission of data and the use, disclosure, and destruction of data and other information received during the negotiation process in order to align with how negotiations are typically conducted by other entities. CMS also believes these requirements are in furtherance of the statutory instruction that CMS develop a process that aims to achieve the lowest MFP for each selected drug.

CMS intends to require that by signing the Agreement, a Primary Manufacturer agrees to use the CMS HPMS and comply with all relevant procedures and policies set forth in the CMS HPMS for utilizing the system.

CMS intends to require that a Primary Manufacturer shall not disclose to the public any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, or any information contained in any concise justification provided with an offer. Further, a Primary Manufacturer shall not disclose to the public any information exchanged verbally during the negotiation period. CMS intends to prohibit audio or video recording of any oral conversations between CMS and a Primary Manufacturer. CMS also intends to require that a Primary Manufacturer shall not use information in the initial offer, including the ceiling price, or the concise justification from the Secretary or any subsequent offer or concise justification, nor information derived from those justifications or offers, for any purposes other than the Medicare Drug Negotiation Program, except as may be required by applicable state or federal law.

Pursuant to section 1193(a)(5) of the Act, CMS intends to require that all information the Primary Manufacturer receives during the negotiation period from CMS shall be destroyed within 30 days of a determination by CMS that the drug or biologic no longer qualifies as a selected drug, except as may be required by applicable state or federal law. CMS believes these policies will increase the chances of effective and successful negotiation in furtherance of the statutory instruction that CMS develop a process that aims to achieve the lowest MFP for each selected drug. The Primary Manufacturer must submit a Certificate of Data Destruction to CMS certifying that all information received from CMS during the negotiation period and potential renegotiation period(s), including the initial offer and any subsequent offers, and the concise justification(s), and any written notes or emails pertaining to negotiations (or renegotiations) with CMS, has been destroyed. This Certificate of Data Destruction must be submitted to CMS within 30 days after a determination by CMS that the drug or biologic no longer qualifies as a selected drug.

CMS is seeking comment on this section. Specifically, CMS is seeking comment on the limitations CMS intends put on the use of information in the initial offer, any subsequent offer,

and any concise justification. CMS is also seeking comment on whether there are possible scenarios where a manufacturer might need to disclose this information. CMS is also seeking comment on the data destruction policies and scenarios where a manufacturer might need to retain certain pieces of information, for example to comply with state or federal laws.

40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years

CMS intends to include the negotiation process and timeline outlined in the Act and in section 60 of this memorandum, including the offer and counteroffer process and the associated timelines, in the Agreement. CMS intends to use the CMS HPMS to share the initial offer and concise justification, any subsequent offer and justification, and to receive any counteroffer(s) from the Primary Manufacturer of a selected drug. A Primary Manufacturer that signs the Agreement would be required to adhere to the process and deadlines described in section 60 of this memorandum.

Under the conditions defined in section 1194(f)(2) of the Act, CMS and a Primary Manufacturer will renegotiate the MFP for a selected drug, beginning with 2028. CMS plans to release guidance related to the renegotiation process in future years.

40.4 Providing Access to the MFP

After entering in an Agreement with CMS and in accordance with section 1193(a) of the Act, the manufacturer of a selected drug that is a covered Part D drug (as defined in section 1860D-2(e) of the Act) must provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act and section 80 of this memorandum) and to pharmacies, mail order services, and other dispensers with respect to such MFP-eligible individuals who are dispensed that drug during a price applicability period.

Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected Part D drug must not exceed the applicable MFP plus any dispensing fees for such drug. In Part D, the negotiated price of a Part D drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point of sale. Therefore, the requirement that the price used for beneficiary cost-sharing and benefit administration cannot exceed the MFP (plus dispensing fees) ensures that Part D MFP-eligible individuals will have access to the MFP at the point of sale. Therefore, while section 1193(a)(1)(A) of the Act specifies that manufacturers must provide access to the MFP to MFP-eligible individuals, as a practical matter that will be accomplished by Part D plan sponsors without additional steps required of the manufacturer.

However, section 1193(a)(1)(A) of the Act also requires that manufacturers provide access to the MFP for selected drugs to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed such drugs. CMS intends to require that the Primary Manufacturer ensure that entities that dispense drugs to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers, have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further discussed in section 90.2 of

this memorandum. CMS intends to define "providing access to the MFP" as ensuring that the amount paid by the dispensing entity for the selected drug is no greater than the MFP.

CMS intends to require that Primary Manufacturers provide access to the MFP in one of two ways: (1) ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. As part of this obligation, the Primary Manufacturer must ensure the MFP is made available to pharmacies, mail order services, and other dispensers for units of the selected drug for which there is a Secondary Manufacturer.

Further, CMS intends to require that a Primary Manufacturer achieve certain outcomes to comply with the requirement under section 1193(a)(1)(A) of the Act to provide access to the MFP:

1. A Primary Manufacturer would be required to submit its process for making the MFP available for the selected drug in writing to CMS at least 30 days before the start of the initial price applicability year for the selected drug. CMS intends to publish these processes on the CMS IRA website. For initial price applicability year 2026, a Primary Manufacturer of a selected drug must send its process for ensuring MFP availability to CMS in writing by December 2, 2025. A Primary Manufacturer would also be required to notify CMS of any changes to its process for making the MFP available at least 30 days before the change goes into effect.
2. CMS intends to monitor for compliance and audit, as needed, to ensure that the MFP is being made available for the selected drug. A Primary Manufacturer would be required to retain for at least ten years from the date of sale any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers for units of selected drug. See section 90.2 of this memorandum for additional details.
3. CMS intends to require that a Primary Manufacturer ensure that pharmacies, mail order services, and other dispensers as well as intermediate entities, such as wholesalers, as applicable, are reimbursed timely for the full amount of the difference between their acquisition cost for the selected drug and the MFP within 14 days. Manufacturers or their contracted entities shall not charge any transaction fee for this process.

CMS intends that the Agreement would not restrict the Primary Manufacturer or Secondary Manufacturer(s) from offering a price lower than the MFP. CMS reiterates that Primary Manufacturers would be responsible for ensuring that the MFP is made available to pharmacies, mail order services, and other dispensers that dispense the selected drug to MFP-eligible individuals, including ensuring that MFP is available for units of the selected drug for which there is a Secondary Manufacturer.

40.4.1 Nonduplication with 340B Ceiling Price

In accordance with 1193(d) of the Act and as further discussed in section 90.2 of this memorandum, the Primary Manufacturer of a selected drug is not required to provide access to

the MFP for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act, if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B ceiling price (defined in section 340B(a)(1) of the PHS Act) is lower than the MFP for such selected drug.

The Primary Manufacturer of a selected drug is required to provide access to the MFP to a covered entity described in section 340B(a)(4) of the PHS Act for MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such 340B ceiling price if the MFP is below the 340B ceiling price for such selected drug. If the 340B ceiling price is subsequently determined to be lower than the MFP, then the manufacturer would be responsible for providing to the covered entity the difference between the MFP and the 340B ceiling price.

40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

After entering in an Agreement with CMS and in accordance with section 1193(a)(5) of the Act, the Primary Manufacturer must comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program. Please reference section 90 of this memorandum for additional details.

40.6. Termination of the Agreement

In accordance with section 1193(b) of the Act, when the Primary Manufacturer enters into the Agreement described in section 40.1 of this memorandum, the Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer considered a selected drug under section 1192(c) of the Act as described in section 70 of this memorandum or is terminated by either party.

40.7 Other Provisions in the Agreement

CMS intends to require that all notices and communications to CMS be sent via email to IRARebateandNegotiation@cms.hhs.gov.

CMS intends to establish that if, after entering in an Agreement with CMS, the Primary Manufacturer of a selected drug transfers the NDA(s)/BLA(s) of the selected drug to another entity, CMS will continue to hold the Primary Manufacturer responsible for all requirements of the Agreement and the requirement to provide access to the MFP unless and until the Primary Manufacturer transfers such requirements to the new holder of the NDA(s)/BLA(s). Further, CMS intends to continue to hold the Primary Manufacturer responsible for any outstanding negotiation rebate liabilities related to the biosimilar delay provision under section 1192(f) of the Act unless and until such liabilities are transferred to the new holder of the NDA(s)/BLA(s). CMS intends to require that notice of any such transfer be sent to CMS at least 30 days before the effective date of such transfer.

CMS intends to require that if any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if the invalid or unenforceable provision(s) were eliminated, and without any effect on any other provisions.

CMS intends to define all days as calendar days unless otherwise specified in statute, guidance, or rulemaking.

50. Negotiation Factors

This section 50 includes additional details on the manufacturer-specific data referenced in section 40.2 of this memorandum. In accordance with sections 1193(a)(4) and 1194(b)(2) of the Act, the Primary Manufacturer of a selected drug that has chosen to sign the Agreement must submit, in a form and manner specified by CMS, information on the non-FAMP for the selected drug (described in section 50.1.1 of this memorandum). The Primary Manufacturer must also submit information on certain factors (described in section 1194(e)(1) of the Act and discussed further in section 50.1 of this memorandum). The Primary Manufacturer will be responsible for aggregating and reporting information from any applicable Secondary Manufacturer(s). In addition, the statute prescribes that CMS also consider available evidence about therapeutic alternatives to the selected drug(s) (described in section 1194(e)(2) of the Act and discussed further in section 50.2 of this memorandum).

While the statute prescribes that CMS consider manufacturer-specific data for the factors described at section 1194(e)(1) of the Act, the statute does not specify what sources CMS must use for the factors described at section 1194(e)(2) regarding therapeutic alternatives to a selected drug. CMS intends to consider evidence about therapeutic alternatives relevant to the factors described in section 1194(e)(2) of the Act submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties. CMS believes that by allowing any interested party to submit data, CMS will be best positioned to identify all available evidence for the factors described at section 1194(e)(2).

CMS intends to release a Negotiation Data Elements ICR, which will describe how CMS intends to collect the data described at sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act. This ICR will include instructions on how Primary Manufacturers and members of the public may submit the relevant data. Comments on the Negotiation Data Elements ICR may be submitted according to the directions listed in the Federal Register once posted. The public will have an opportunity to submit comments on this ICR for 60 days after notice is published in the Federal Register followed by an additional opportunity to submit comments for 30 days after revisions and republication.

CMS is including the definitions that CMS intends to adopt for the purposes of describing the data to be collected for use in the Negotiation Program under sections 1193(a)(4)(A) and 1194(e)(1) of the Act in Appendix C of this memorandum.

In accordance with section 1191(d)(5)(A) of the Act, the data described in sections 50.1 and 50.2 of this memorandum for drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023.

50.1 Manufacturer-Specific Data

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP of a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers, as discussed in section 60 of this memorandum. These factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Submission of these data is required by the Primary Manufacturer if an Agreement is signed; details related to the submission process are discussed in section 40.2 of this memorandum.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by October 2, 2023:

1. Research and development costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
3. Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s) (with the exception of costs related to the acquisition of the selected drug, which would be reported only for the Primary Manufacturer).

As noted above, CMS intends for the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-FAMP, current unit costs of production and distribution, and certain data within market data and revenue and sales volume data for the selected drug.

Please see Appendix C of this memorandum for a list of definitions that CMS intends to adopt for the purposes of describing these data to be collected for use in the Negotiation Program.

50.1.1 Non-FAMP Data

The Primary Manufacturer must submit data on non-FAMP for the selected drug for the Primary Manufacturer and any Secondary Manufacturer(s), as required under section 1193(a)(4)(A) of the Act. CMS will be collecting these data through the Negotiation Data Elements ICR described above. Specifically, for initial price applicability year 2026, the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar year 2021, or in the case there is no non-FAMP for the selected drug in calendar year 2021, the non-FAMP,

unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of the first full year following market entry of such drug. The use of these data to calculate the ceiling for the MFP is further described in section 60.2 of this memorandum. Details on how CMS intends to define the parameters of the non-FAMP data collection are included in Appendix C of this memorandum and will also be included in the forthcoming Negotiation Data Elements ICR.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

As noted above, section 1194(e)(2) of the Act directs CMS to consider evidence about alternative treatments to the selected drug, as available, including:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, herein referred to as "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Section 1194(e)(2) of the Act additionally requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Information submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties, or other information found by CMS that treats extending the life of individuals in these populations as of lower value, for example certain uses of quality-adjusted life-years (QALYs), will not be used in the negotiation process. In instances where a study uses QALYs in a life-extension context but has clearly separated this use of QALYs from other evidence in the report (e.g., clinical effectiveness, risks, harms, etc.) that is relevant to the factors listed in section 1194(e)(2) of the Act, CMS intends to consider such separate evidence. CMS will ask entities submitting information to indicate whether or not their submission contains information from studies that use QALYs in a life-extension context. CMS is soliciting comment on other metrics, in addition to QALYs, that may treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill and that CMS should also exclude from consideration when developing offers and reviewing counteroffers.

The Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, and other interested parties, may submit information on selected drugs and their therapeutic alternatives (specifically pharmaceutical therapeutic alternatives, as described in detail in section 60.3.1 of this memorandum), including information

on whether the selected drug represents a therapeutic advance over its therapeutic alternatives, prescribing information for the selected drug and its therapeutic alternatives, comparative effectiveness data for the selected drug and its therapeutic alternatives, information about the impact of the selected drug and its therapeutic alternatives on specific populations, and/or information on whether the selected drug and its therapeutic alternatives address unmet medical need, as described in section 1194(e)(2) of the Act.

CMS additionally intends to review existing literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts on these topics (described in section 60.3.1 of this memorandum) in considering available evidence about alternative treatments to the selected drug. When reviewing the literature, CMS intends to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. CMS will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., has sufficient sample size) to answer the primary clinical question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses.

In particular, CMS intends to consider research on and real-world evidence relating to Medicare populations, including on individuals with qualifying disabilities, patients with end-stage renal disease (ESRD), and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, CMS will prioritize research specifically designed to focus on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus.

All information on the factors described in section 1192(e)(2) of the Act related to drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023.

60. Negotiation Process

In accordance with section 1194(b)(1) of the Act, CMS intends to develop and use a consistent methodology and process for negotiation that "aims to achieve the lowest maximum fair price for each selected drug." This section 60 describes the negotiation process, including the development of the written initial offer, the process for making such offer and providing a concise justification to the Primary Manufacturer of a selected drug, the process and requirements for accepting an offer or providing a counteroffer, the potential for 1-3 meetings between CMS and the Primary Manufacturer, the conclusion of negotiation, and the publication of the MFP.

60.1 Establishment of a Single Proposed MFP for Negotiation Purposes

In accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b), as applicable, for such drug and year. CMS interprets this language to refer to a single price negotiation for a selected drug with respect to its price applicability period. Accordingly, CMS intends to identify a single price for use at each step in the negotiation process described in this section 60, meaning each offer and counteroffer, described in section 60.4 of this memorandum, would include a single price, even for a selected drug with multiple dosage forms and strengths. Once the MFP has been determined, section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply the MFP across different dosage forms and strengths of a selected drug, as applicable.

For the purposes of determining a single price included in an initial offer (including evaluating clinical benefit compared to therapeutic alternatives, as discussed in section 60.3 of this memorandum) and conducting the negotiation, CMS intends to base the single price on the cost of the selected drug per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection – or per volume or weight-based metric), weighted across dosage forms and strengths, as applicable. For example, if the selected drug is available in a tablet form taken daily as well as an injection form taken every other month, CMS would base the single price for the initial offer on the average cost of (1) 30 tablets and (2) one injection divided by 2 (half the cost of one injection), weighted by number of 30-day equivalents for each presentation as reflected in Medicare Part D utilization during the 12-month period ending May 31, 2023. This approach of negotiating a single price across all dosage forms and strengths aligns with the statutory requirement to negotiate an MFP for a selected drug. CMS believes this will also allow for a more direct comparison with therapeutic alternatives, which might have different dosage forms, strengths, and frequency of use than the selected drug.

CMS is soliciting comment on its intended approach to identify a single price for use at each step in the negotiation process. Specifically, CMS seeks comment on the advantages and disadvantages of converting to a price per 30-day equivalent supply. CMS also solicits comment on whether there are other approaches that allow CMS to calculate a single price across dosage forms and strengths and allow for a more direct comparison with therapeutic alternatives, which might have different dosage forms, strengths, and frequency of use than the selected drug.

Section 60.5 of this memorandum describes the methodology to translate the MFP once finalized (which, per above, CMS intends to be an average price per 30-day equivalent supply for the selected drug) back into per unit (e.g., tablet) prices at the dosage form and strength level for the purposes of publishing per unit MFPs for the different dosage forms and strengths of the selected drug. In addition to the description of that methodology included in this memorandum, CMS will share the inputs behind that methodology specific to the selected drug with the Primary Manufacturer of the selected drug during the negotiation such that the Primary Manufacturer will have visibility into the implied unit prices based on the MFP for each dosage form and strength throughout the negotiation process (i.e., any offer or counteroffer that identifies a single price

would be clearly translatable to per unit prices at the dosage form and strength unit level). Please see Section 60.5 of this memorandum for details.

60.2 Limitations on Offer Amount

In accordance with section 1194(b)(2)(F)(i) of the Act, in negotiating the MFP of a selected drug, with respect to initial price applicability year 2026, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. This section 60.2 of this memorandum provides details on the determination of the ceiling for the MFP and comparison of the ceiling to the MFP.

60.2.1 Determination of the Ceiling for the MFP

In accordance with section 1194(c) of the Act, for initial price applicability year 2026, the ceiling for the MFP for a selected drug shall not exceed the lower of the following:

- As described in section 60.2.2 of this memorandum, an amount equal to the sum of the plan specific enrollment weighted amounts; or

- As described in section 60.2.3 of this memorandum, an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.[26]

CMS interprets the language in section 1194(c)(1)(A) of the Act to mean it should calculate a single amount across all dosage forms and strengths of the selected drug for the sum of the plan specific enrollment weighted amounts and for the applicable percent of the average non-FAMP in order to determine which one is lower and will serve as the ceiling for the MFP. In order to determine whether the sum of the plan specific enrollment weighted amounts or the applicable percent of the average non-FAMP will be used to calculate the ceiling for the MFP, CMS intends to aggregate the amounts determined for each applicable NDC-11 for the selected drug to calculate a single amount – separately for each methodology – across dosage forms, strengths, and package sizes of the selected drug. These amounts can then be directly compared, and the ceiling for the single MFP of the selected drug (including all of its dosage forms and strengths) would be based on the lower amount.

Once the ceiling has been established (based on either the sum of plan specific enrollment weighted amounts or the applicable percent of the average non-FAMP), CMS plans to apply the

[26] The September 2021 CPI-U, not seasonally unadjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.202 percent. Data retrieved from https://www.bls.gov/cpi/data.htm on March 8, 2023.

single ceiling across dosage forms and strengths to yield dosage form and strength-specific ceilings. As described in section 60.2.4 of this memorandum, these dosage form and strength-specific ceilings would then be applied to the MFP per 30-day equivalent supply for each dosage form and strength calculated in step 9 of section 60.5, to ensure the MFP applied to each dosage forms and strength does not exceed the ceiling.

To calculate dosage form and strength-specific ceilings and a single ceiling across dosage forms and strengths of the selected drug, CMS intends to do the following:

1. calculate a single ceiling price per 30-day equivalent supply across the NDC-11s for each specific dosage form and strength of the selected drug; and
2. calculate a single ceiling price per 30-day equivalent supply across all dosage forms and strengths of the selected drug.

Using the price per 30-day equivalent supply to calculate these two amounts facilitates aggregation across dosage forms and strengths of a selected drug where units (e.g., mg versus ml) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ. Sections 60.2.2 and 60.2.3 of this memorandum describe this process for calculating the sum of plan specific enrollment weighted amounts and for calculating the applicable percent of the average non-FAMP, respectively, and section 60.2.4 describes the selection of the ceiling for the single MFP and comparison of the dosage form and strength-specific ceiling to the MFP applied across dosage forms and strengths.

60.2.2 Sum of Plan Specific Enrollment Weighted Amounts

In accordance with section 1194(c)(1)(B)(i) of the Act, CMS will calculate for a selected drug an amount equal to the sum of the plan specific enrollment weighted amounts determined using the methodology described in section 1194(c)(2) of the Act. Plan sponsors report Part D PDE data to CMS at the NDC-11 level. Sponsors also report Direct and Indirect Remuneration (DIR) data to CMS at the NDC-11 level in the annual Detailed DIR Report. CMS intends to use these reported data for plan year 2022, which is the most recent year for which data will be available, for the purpose of determining the sum of plan specific enrollment weighted amounts for a selected drug for initial price applicability year 2026.

CMS intends to calculate the sum of plan specific enrollment weighted amounts in two stages for purposes of determining the ceiling for the MFP and, if applicable, to compare this ceiling to the MFP applied across dosage forms and strengths as described in section 60.2.4 of this memorandum. First, CMS would calculate the sum of plan specific enrollment weighted amounts for each dosage form and strength of the selected drug. Second, CMS would calculate the sum of plan specific enrollment weighted amounts across dosage forms and strengths of the selected drug. The amounts calculated at each stage are for a 30-day equivalent supply.

To determine the sum of plan specific enrollment weighted amounts for each dosage form and strength and across all dosage forms and strength of the selected drug, CMS intends to conduct the following steps.

Steps 1 through 7 would result in the sum of the plan specific enrollment weighted amounts for each dosage form and strength of the selected drug:

1. For each Part D plan, CMS would identify the PDE data for the selected drug for 2022 (that is, PDE records with dates of service during the period beginning on January 1, 2022 and ending on December 31, 2022).
2. For each Part D plan, CMS would sum the negotiated price amounts (as defined in 42 CFR 423.100) and the estimated rebate at point of sale amounts (ERPOSA) across the PDE records for each of the NDC-11s of each dosage form and strength. CMS would also calculate the 30-day equivalent supply for each PDE record and sum the 30-day equivalent supply across the PDE records for each of the NDC-11s of each dosage form and strength.
3. For each Part D plan, CMS would sum the total DIR amounts found in the 2022 Detailed DIR Report for all NDC-11s of each dosage form and strength and subtract the total ERPOSA calculated in step 2 to avoid double counting price concessions applied at the point of sale to calculate the total DIR amount for each dosage form and strength of the selected drug.
4. For each Part D plan and each dosage form and strength of the selected drug, CMS would subtract the total DIR amount calculated in step 3 from the sum of the negotiated price amounts calculated in step 2 and then divide by the total 30-day equivalent supply of the dosage form and strength, also determined in step 2. This calculation results in the price per 30-day equivalent supply of the dosage form and strength of the selected drug, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan.
5. Separately, CMS would identify the total number of individuals enrolled in all Part D plans in December 2022, and the total number of individuals enrolled in each Part D plan in that month.[27]
6. For each Part D plan, CMS would divide the total number of Part D beneficiaries enrolled in the Part D plan during December 2022 as identified in step 5 by the total number of individuals enrolled in all Part D plans in December 2022 also as identified in step 5, and multiply this quotient by the price for a 30-day equivalent supply, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan, calculated in step 4, to arrive at the plan specific enrollment weighted amount.
7. CMS would then sum the amounts calculated in step 6 across all Part D plans to calculate the sum of the plan specific enrollment weighted amounts for each dosage form and strength of the selected drug.

Steps 8 through 10 result in the sum of the plan specific enrollment weighted amounts for the selected drug across all dosage forms and strengths:

[27] CMS conducted an analysis of monthly Part D plan enrollment changes during 2022 and determined that monthly enrollment changes were the lowest from November to December, so CMS chose December as the most stable month to identify enrollment. The choice of one month to identify enrollment also allows the weights calculated in step 6 to sum to one.

8. CMS would use the Part D PDE data for 2022 to calculate the total 30-day equivalent supply for each dosage form and strength of the selected drug across all Part D plans. Also, CMS would use the same data to calculate the total 30-day equivalent supply of the selected drug across all dosage forms and strengths and all Part D plans.
9. For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for the dosage form and strength by the total 30-day equivalent supply across all dosage forms and strengths of the selected drug as identified in step 8, and multiply this quotient by the sum of the plan specific enrollment weighted amounts for the dosage form and strength as calculated in step 7.
10. CMS would then sum amounts calculated in step 9 across all dosage forms and strengths of the selected drug to calculate the sum of the plan specific enrollment weighted amounts for the selected drug.

CMS would include all Part D plans that have PDE data for the selected drug in this calculation. Because CMS would have no PDE data for Part D plans in the following circumstances, such Part D plans would, by definition, be excluded from the calculation of the plan specific enrollment weighted amounts: (1) plans that have no utilization for the selected drug and (2) plans that have no enrollment for 2022.[28]

60.2.3 Average Non-Federal Average Manufacturer Price

In accordance with section 1194(c)(1)(C)(i) of the Act, for initial price applicability year 2026, CMS will calculate an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.[29]

For this calculation, CMS intends to use the non-FAMP of each NDC-11 for the selected drug for each quarter of calendar year 2021 that is submitted to CMS by the Primary Manufacturer pursuant to section 1193(a)(4)(A) of the Act (as described in section 50.1 of this memorandum). CMS also intends to use NDC-11 level unit volume data for each quarter of calendar year 2021 submitted to CMS by the Primary Manufacturer (also described in section 50.1 of this memorandum). Lastly, CMS would use 2022 Part D PDE data submitted to CMS at the NDC-11 level by Part D plan sponsors to determine the 30-day equivalent supply for each NDC-11 of the selected drug. In order to directly compare the amount calculated based on the applicable percent of average non-FAMP and the amount calculated based on the sum of the plan-specific enrollment weighted amounts (as described in this section 60.2.2 above), CMS intends to base the average non-FAMP calculations on a 30-day equivalent supply and intends to use the same

[28] CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.
[29] The September 2021 CPI-U, not seasonally adjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.2 percent. Data retrieved from https://www.bls.gov/cpi/data.htm on March 8 2023.

data source for weighting both the sum of the plan-specific enrollment weighted amounts and the average non-FAMP to determine which amount is lower.

CMS intends to calculate the applicable percent of the average non-FAMP in two stages for purposes of determining the ceiling for the MFP and, if applicable, to compare the applicable percent of the average non-FAMP to the MFP applied across dosage forms and strengths as described in section 60.2.4 of this memorandum. First, CMS would calculate the applicable percent of the average non-FAMP for each dosage form and strength of the selected drug. Second, CMS would calculate the applicable percent of the average non-FAMP across dosage forms and strengths of the selected drug. The amounts calculated in each stage are for a 30-day equivalent supply.

To determine the applicable percent of the average non-FAMP for each dosage form and strength and across all dosage forms and strengths of the selected drug, CMS intends to conduct the following steps.

Steps 1 through 9 would result in the applicable percent of the average non-FAMP for each dosage form and strength of the selected drug:

1. In order to calculate an average non-FAMP that is comparable to the sum of plan specific enrollment weighted amounts described in section 60.2.2 of this memorandum, CMS would compare the non-FAMP unit type (e.g., tablet) to the PDE units (i.e., each, milliliter, and grams). In instances where the units are different, CMS would convert the non-FAMP unit type to the PDE units so that the two amounts (average non-FAMP and sum of plan specific enrollment weighted amounts) represent the same quantity of the selected drug.[30]
2. CMS would calculate the non-FAMP per unit by dividing the non-FAMP per package by the total number of units per package for that NDC-11.
3. For each NDC-11 of the selected drug and for each quarter during calendar year 2021, CMS would divide the total unit volume (calculated as the product of the total number of packages sold by the number of units per package for that NDC-11) in that quarter by the total unit volume across all four quarters during calendar year 2021, and multiply this quotient by the non-FAMP.
    - Note: In the case that there is not a non-FAMP available for such drug for calendar year 2021, CMS would use the non-FAMP and total unit volumes for the quarters of the first full year following the market entry for such drug.
4. For each NDC-11 of the selected drug, CMS would sum the amounts calculated in step 3 across quarters to calculate the average non-FAMP for that NDC-11 in calendar year 2021. CMS believes steps 3 and 4 are necessary to account for unit volume fluctuations that may occur across quarters for each NDC-11.

[30] PDE units are industry standard National Council for Prescription Drug (NCPDP) defined values of each, milliliter, and grams: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

5. For each NDC-11 of the selected drug, CMS would divide the total unit volume in calendar year 2021 for that NDC-11 by the total unit volume in calendar year 2021 for all NDC-11s of the same dosage form and strength, and multiply this quotient by the average non-FAMP in calendar year 2021 for that NDC-11 calculated in step 4.
6. For each dosage form and strength of the selected drug, CMS would sum the amounts calculated in step 5 to calculate the average non-FAMP for that dosage form and strength in calendar year 2021. CMS believes steps 5 and 6 are necessary to account for unit volume fluctuations that may occur across NDC-11s of a dosage form and strength.
7. For each dosage form and strength of the selected drug, CMS would then multiply the average non-FAMP in calendar year 2021 calculated in step 6 by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 to September 2022 as specified in section 1194(c)(1)(C)(i) of the Act.
    - Note: In the case that there is not a non-FAMP available for that dosage form and strength of the selected drug for calendar year 2021, CMS would use the percentage increase from December of the first full year following the market entry for that dosage form and strength instead of September 2021, as required under section 1194(c)(1)(C)(i) of the Act.
8. After CMS has calculated the average non-FAMP in calendar year 2021 for each dosage form and strength of the selected drug, adjusted for inflation, CMS would apply the applicable percent specified in section 1194(c)(1)(C) of the Act for the monopoly type determined for the selected drug based on its initial approval date (described in section 30.1 of this memorandum). CMS believes applying the applicable percent in this step for each dosage form and strength is appropriate because it would allow CMS to apply the amount determined in the following step (step 9) to the MFP applied across dosage forms and strengths as described in section 60.2.4 of this memorandum. Furthermore, applying the applicable percent here, in step 8, results in the same step 11 amount as would result if CMS were to apply the applicable percent in step 11. The definition of each monopoly type and the applicable percentage are described below for initial price applicability year 2026. CMS notes that the extended monopoly type is not discussed below because the definition of extended-monopoly drug under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with the Secretary with respect to an initial price applicability year that is before 2030. CMS intends to interpret this to mean that no selected drug would be considered an extended-monopoly drug for purposes of the Negotiation Program prior to initial price applicability year 2030.

Figure 2: Monopoly Types and Applicable Percentage for Initial Price Applicability Year 2026

Monopoly Type	Definition	Applicable Percentage	Note
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act)[31]	For initial price applicability year 2026, a selected drug or vaccine that is not a long-monopoly drug.	75%	The first approval date, under section 505(c) of the FD&C Act, associated with the initial FDA application number for the active moiety (or fixed combination drug) must be after September 1, 2007 and before September 1, 2016. The first licensure date, under section 351(a) of the PHS Act, associated with the initial FDA application number for the active ingredient (or fixed combination drug) must be after September 1, 2007 and before September 1, 2012.
Long-monopoly drug (section 1194(c)(5)(A) of the Act)	A selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term 'long-monopoly drug' does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	40%	The first approval date under section 505(c) of the FD&C Act or the first licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or fixed combination drug) must be on or before September 1, 2007.

9. CMS would then multiply the average non-FAMP for calendar year 2021 for each dosage form and strength of the selected drug, adjusted for inflation and with the applicable percent applied calculated in step 8, by the quotient of the total number of units of that dosage form and strength divided by the total 30-day equivalent supply (i.e., this quotient would represent the average units per 30-day supply equivalent) for that dosage form and strength calculated from Part D PDE data for 2022 to determine the average non-FAMP

[31] Because the definition of extended-monopoly drug at section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with the Secretary with respect to an initial price applicability year before 2030, for initial price applicability 2026, any drug, biological product, or vaccine that is not considered a long-monopoly drug will be considered a short monopoly drug.

for a 30-day equivalent supply of that dosage form and strength of the selected drug. As noted above in section 60.2.1 of this memorandum, CMS believes calculating the average non-FAMP for a 30-day equivalent supply is necessary to account for potential different units and treatment regimens across dosage forms and strengths.

Steps 10 and 11 would calculate the applicable percent of the average non-FAMP across all dosage forms and strengths of the selected drug:

10. For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for the dosage form and strength by the total 30-day equivalent supply across all dosage forms and strength of the selected drug calculated from Part D PDE data for 2022, and multiply this quotient by the average non-FAMP for that dosage form and strength calculated in step 9.
11. CMS would then sum amounts calculated in step 10 across dosage forms and strengths of the selected drug to calculate the applicable percent of the average non-FAMP for the selected drug.

60.2.4 Selection and Application of the Ceiling for the MFP

CMS intends to compare the values calculated in step 10 of section 60.2.2 of this memorandum (sum of plan specific enrollment weighted amounts) and step 11 of section 60.2.3 of this memorandum (applicable percent of the average non-FAMP) and select the lower value as the ceiling price for the selected drug. Once CMS has identified whether the ceiling price would be determined by the sum of plan specific enrollment weighted amounts or the applicable percent of the average non-FAMP, CMS intends to ensure that the MFP per 30-day equivalent supply for each dosage form and strength of the selected drug calculated in step 9 of the methodology described in section 60.5 of this memorandum is not above the statutorily defined ceiling by comparing it to the applicable ceiling for a 30-day equivalent supply for that dosage form and strength of the selected drug calculated in either step 7 of section 60.2.2 or step 9 of section 60.2.3 (depending on which ceiling is selected).

This approach would allow for selection of a single ceiling for the MFP for the selected drug as required by section 1194(c)(1)(A), but also enable CMS to determine if the initial offer or counteroffer, as applicable, applied across dosage forms and strengths, is at or below the ceiling price specific to each dosage form and strength of the selected drug.

CMS considered the alternative of applying a single ceiling on the MFP across all dosage forms and strengths of the selected drug, but concluded that prices may vary across dosage forms and strengths in a meaningful way, and that this variation should be maintained.

For example, the ceiling price specific to a given dosage form and strength of the selected drug (as calculated in step 7 of section 60.2.2 or step 9 of section 60.2.3, depending on which ceiling is selected) may be higher than the single ceiling price for the selected drug (as calculated in step 10 of section 60.2.2 or step 11 of section 60.2.3, depending on which ceiling is selected). The alternative approach of applying a single ceiling to the MFP across all dosage forms and

strengths of the selected drug would constrain the MFP for that dosage form and strength more significantly than the approach of applying a ceiling price specific to that dosage form and strength.

The counterexample where the ceiling price specific to a given dosage form and strength of the selected drug (as calculated in step 7 of section 60.2.2 or step 9 of section 60.2.3, depending on which ceiling is selected) is lower than the single ceiling price for the selected drug (as calculated in step 10 of section 60.2.2 or step 11 of section 60.2.3, depending on which ceiling is selected) is also possible. Under this example, the alternative approach of applying a single ceiling to the MFP across all dosage forms and strengths of the selected drug would constrain the MFP for that dosage form and strength less significantly than the approach of applying a ceiling price specific to that dosage form and strength.

Under both examples, the alternative of applying a single ceiling price for the selected drug would limit the degree to which price variation between different dosage forms and strengths is maintained in the application of the ceiling price to the MFP.

60.3 Methodology for Developing an Initial Offer

Section 1194(e) of the Act directs CMS to consider certain factors related to manufacturer-specific data and available evidence about therapeutic alternatives as the basis for determining offers and counteroffers in the negotiation process. While the statute requires CMS to provide an initial offer and a justification, it does not specify how CMS should determine an initial offer nor how or to what degree each factor should be considered.

As discussed in greater detail below, for the purposes of determining an initial offer, CMS intends to (1) identify therapeutic alternative(s), if any, for the selected drug as described in section 60.3.1 of this memorandum; (2) use the Part D net price for the therapeutic alternative(s) that is a Part D drug and/or the Part B average sales price (ASP) for the therapeutic alternative(s) that is a Part B drug to determine a starting point for developing an initial offer as described in section 60.3.2 of this memorandum; (3) evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)) for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2) of the Act, including whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations, as described in section 60.3.3 of this memorandum (resulting in the "preliminary price"); and (4) further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act (described in section 60.3.4 of this memorandum) to determine the initial offer price.

CMS will not make or accept any offers for the MFP that are above the statutorily defined ceiling price described in section 60.2.1 of this memorandum.

60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication

For initial price applicability year 2026, CMS intends to identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act for a selected drug, using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. CMS intends to consider off-label use when identifying indications if such use is included in nationally recognized, evidence-based guidelines and recognized by CMS-approved Part D compendia.[32]

For each indication of the selected drug, CMS then intends to identify a pharmaceutical therapeutic alternative(s). CMS considered evaluating non-pharmaceutical therapeutic alternatives; however, for initial price applicability year 2026, the agency plans to only consider therapeutic alternatives that are covered Part D or Part B drugs or biologics. CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials. To identify potential therapeutic alternatives for the indications of a selected drug, CMS intends to use data submitted by the Primary Manufacturer and the public, FDA-approved indications, indications included in CMS-approved Part D compendia, widely accepted clinical guidelines, and peer-reviewed studies.

CMS also intends to consider clinical evidence available through literature searches when a therapeutic alternative has not yet been incorporated into nationally recognized, evidence-based guidelines. CMS intends to begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes.

60.3.2 Developing a Starting Point for the Initial Offer

CMS considered several options for what price should be used as the starting point for developing the initial offer. Options considered include the use of the Part D net price(s) and/or the ASP(s) of therapeutic alternative(s), if any, to the selected drug, the unit cost of production and distribution for the selected drug, the ceiling price for the selected drug (as described in section 60.2 of this memorandum), a domestic reference price for the selected drug (e.g., the Federal Supply Schedule price), or a "fair profit" price for the selected drug based on whether research and development costs have been recouped and margin on unit cost of production and distribution. Under any of these options, the initial offer and final MFP would be capped at the statutory ceiling.

After considering these options, CMS intends to use the Part D net price(s) ("net price(s)") and/or ASP(s) of therapeutic alternative(s) for the selected drug, as applicable, as the starting point for developing the MFP initial offer unless this net price or ASP is greater than the statutory ceiling (described in section 60.2 of this memorandum). CMS intends to identify the

[32] CMS-approved Part D compendia are listed in Chapter 6 of the Prescription Drug Benefit Manual as described in 1927(g)(1)(B)(i) of the Act.

price of each therapeutic alternative that is a covered Part D drug net of all price concessions received by any Part D plan or pharmacy benefit manager on behalf of the Part D plan by using Part D PDE data and detailed DIR report data, similar to the calculation of the ceiling price using the sum of plan specific enrollment weighted amounts described in section 60.2.2 of this memorandum. In taking this approach, CMS acknowledges that the therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit, however, using net prices and ASPs of therapeutic alternatives enables CMS to start developing the initial offer within the context of the cost and clinical benefit of a group of drugs that treat the same disease or condition. By using the price(s) of the selected drug's therapeutic alternative(s), CMS would be able to focus the initial offer on clinical benefit by adjusting this starting point relative to whether the selected drug offers more, less, or similar clinical benefit compared to its therapeutic alternatives. The other potential options considered do not reflect the cost of therapeutic alternatives, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries.

If there is one therapeutic alternative for the selected drug, CMS intends to use the net price or ASP, as applicable, of the therapeutic alternative as the starting point to develop CMS' initial offer for the MFP if it is lower than the ceiling. If there are multiple therapeutic alternatives, CMS intends to consider the range of net prices and/or ASPs as well as the utilization of each therapeutic alternative to determine the starting point within that range. If the selected drug has no therapeutic alternative, if the price of the therapeutic alternatives identified is above the statutory ceiling for the MFP (described in section 60.2 of this memorandum), or if there is a single therapeutic alternative with a price above the statutory ceiling, then CMS intends to determine the starting point for the initial offer based on the Federal Supply Schedule[33] (FSS) or "Big Four Agency"[34] price ("Big Four price"). If the FSS and Big Four prices are above the statutory ceiling, then CMS intends to use the statutory ceiling as the starting point for the initial offer.

CMS is soliciting comment on this intended approach to determining a starting point for developing the initial offer. Specifically, CMS is soliciting comments on the advantages and disadvantages of using net prices and/or ASPs as the starting point for the initial offer for selected drugs with at least one therapeutic alternative and the Federal Supply Schedule or Big Four price for selected drugs with no therapeutic alternative or for selected drugs with therapeutic alternatives with net prices and/or ASPs greater than the statutory ceiling. CMS is also soliciting comment on other starting points for the initial offer, including but not limited to other domestic reference prices, along with their disadvantages and advantages. Lastly, in the

[33] The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsa-schedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20government.

[34] The Big Four price is the maximum price that any "Big Four Agency" (the Department of Veteran's Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard) is required to pay. See: https://www.cbo.gov/publication/57007.

event that there are multiple therapeutic alternatives for the selected drug, CMS is soliciting comment on how to consider the range of net prices and/or ASPs and utilization of each therapeutic alternative to determine a single starting point for developing the initial offer.

60.3.3 Adjusting the Starting Point Based on Clinical Benefit

To evaluate the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), as applicable, CMS intends to broadly evaluate the body of clinical evidence, including data received from the public and manufacturers as described in section 50.2 of this memorandum, and data identified through a CMS-led literature review. CMS may also analyze Medicare claims or other pharmaceutical drug datasets for utilization patterns, clinical data, or other information relevant to the selected drug and its therapeutic alternative(s) and may consult with clinical and academic experts.

This approach provides a pathway for CMS to consider the multitude of information expected from public input, including but not limited to peer-reviewed research, expert reports or whitepapers, clinician expertise, real-world evidence, and patient experience. This approach also provides flexibility to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

Once the starting point for the initial offer has been established and evidence on clinical benefit has been considered, CMS intends to adjust the starting point for the initial offer based on the review of the clinical benefit (this adjusted price is referred to herein as the "preliminary price"). Per statute, CMS will not use evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill; this includes QALYs when used in association with life extension. CMS considered employing both a qualitative approach (e.g., adjusting the starting point upward or downward relative to the clinical benefit offered by the selected drug compared to its therapeutic alternatives) and a more thoroughly pre-specified quantitative approach. CMS intends to use a qualitative approach to preserve flexibility in negotiation, including the ability to consider nuanced differences between different drugs, for example interactions with other treatments commonly prescribed simultaneously for a condition or disease, and other factors that might not be captured in a more thoroughly pre-specified quantitative approach.

60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

To consider comparative effectiveness between a selected drug and its therapeutic alternative(s), CMS intends to (1) identify outcomes to evaluate for each indication of the selected drug, and (2) consider the safety profile of the selected drug and the therapeutic alternative(s). CMS intends to consider health outcomes, intermediate outcomes, surrogate endpoints,[35] patient-reported

[35] A surrogate endpoint is an indirect measure of whether a treatment works. Surrogate endpoints may be used in clinical trials when a clinical outcome would take too long to study, in cases where the relationship between the

outcomes, and patient experience when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s). When reviewing such information, as noted above CMS will not use evidence in a manner that treats extending the life of any individual as lower value than the life of another individual; this includes QALYs when used in association with life extension. Health outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to therapeutic alternatives. CMS also intends to consider validated surrogate endpoints that predict a relevant health outcome (e.g., lower blood pressure reducing the risk of stroke) and intermediate outcomes that indicate a change in health outcomes. Health outcomes such as changes in symptoms or other factors that are of importance to a person, and patient-reported outcomes would also be considered. CMS intends to focus the review of clinical benefit on outcomes of particular importance to the condition or disease being treated by the selected drug and will determine such outcomes from the CMS-led literature review and information submitted by manufacturers and the public through the Negotiation Data Elements ICR, described in section 50 of this memorandum.

In all cases, CMS intends to consider applicable evidence and other input collectively and within the context of the course of care for the condition(s) or disease(s) that the selected drug is indicated to treat. As noted previously, this approach provides flexibility to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

CMS will also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations as required by section 1194(e)(2)(C) of the Act. To do so, CMS intends to prioritize studies focused on the impact of the selected drug and its therapeutic alternative(s) on individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations represented among Medicare beneficiaries. Further, CMS will consider whether the selected drug fills an unmet medical need, which CMS intends to define as treating a disease or condition in cases where very limited or no other treatment options exist.

CMS intends to determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression). CMS understands that a selected drug can be first in class,[36] however, if other drugs have become available since the selected drug's initial release, CMS will compare therapeutic alternatives with the same indication within or beyond the selected drug's class as described in this section. In accordance with section 1194(e)(2)(A) of the Act, CMS will review the analyses detailed above for each indication for the selected drug and its therapeutic alternative(s) and determine, based on the

surrogate endpoint and clinical benefit is well understood, or in cases where using a clinical endpoint would be unethical. See: https://www.fda.gov/drugs/development-resources/surrogate-endpoint-resources-drug-and-biologic-development.

[36] First in class drugs are those that have a new mechanism of action, defined by the National Cancer Institute as "a term used to describe how a drug or other substance produces an effect in the body." See https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action.

relevant information and evidence, what the difference in clinical benefit is between the selected drug and the therapeutic alternative(s).

As previously noted, CMS intends to take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug and its therapeutic alternative(s) as well as the patient population(s) taking the selected drug. For each selected drug, the applicable starting point would be adjusted based on the totality of the relevant information and evidence submitted and gathered through the agency's analysis based on the clinical benefit the selected drug provides. Because the extent of clinical benefit may vary across different indications, CMS may adjust the initial offer based on the clinical benefit for an individual indication in cases where the clinical benefit of the selected drug is notably different than the therapeutic alternative for that specific indication.

60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives

For selected drugs with no therapeutic alternatives, CMS intends to adjust the starting point for the initial offer based on the extent to which the selected drug fills an unmet medical need. CMS will consider unmet medical need separately for each indication. A selected drug will be considered to meet an unmet medical need for an indication included in the analysis in cases where limited or no treatment options exist.

Similar to a selected drug with at least one therapeutic alternative, the starting point for a selected drug without a therapeutic alternative would also be adjusted based on the totality of relevant information and evidence submitted and gathered through the agency's analysis based on the clinical benefit the selected drug provides

60.3.4 Consideration of Manufacturer-Specific Data

Under section 1194(e)(1) of the Act, CMS must also consider factors reported by the Primary Manufacturer, described in section 50.1 of this memorandum. CMS will consider these data and may adjust the preliminary price (described in section 60.3.3 of this memorandum), as needed to address these manufacturer-specific data elements. These data elements include (1) research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug; and (5) market data and revenue and sales volume data for the drug in the United States.

In considering element (1) above on research and development costs, CMS intends to consider the extent to which the Primary Manufacturer has recouped its research and development costs. CMS will compare the research and development costs and the global, net revenue reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its research and development costs. For example, if a Primary Manufacturer has not

recouped its research and development costs, CMS could consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its research and development costs, CMS may consider adjusting the preliminary price downward. CMS intends to use the research and development costs reported by the Primary Manufacturer, including the assumptions and calculations in the accompanying narrative text, the indication(s) for the selected drug, and other factors as described in the forthcoming Negotiation Data Elements ICR and in Appendix C of this memorandum.

In considering element (2) on current unit costs of production and distribution, CMS intends to consider the relationship between the preliminary price and the unit price of production and distribution. For example, CMS may consider adjusting the preliminary price downward if the unit cost of production and distribution is lower than the preliminary price, or upward if the preliminary price is close to the unit costs of production and distribution. Again, CMS may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug when determining if an adjustment would be appropriate.

In considering element (3) on prior Federal financial support, CMS intends to consider the extent to which the Primary Manufacturer benefited from Federal financial support. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

In considering element (4) on patent applications, exclusivities, and applications and approvals for the selected drug, CMS intends to consider the length of the available patents and exclusivities before the selected drug may no longer be single source. For example, if the selected drug has patents and exclusivities that will last for a number of years, CMS may consider adjusting the preliminary price downward.

Finally, in considering element (5) on market data and revenue and sales volume data for the U.S., CMS intends to consider how the data compare to the CMS preliminary price. For example, if the average commercial net price is lower than the preliminary price, CMS may consider adjusting the preliminary price downward.

Appendix C of this memorandum includes a list of definitions that CMS intends to adopt for the purposes of describing the data to be collected with respect to the data elements listed in section 1194(e)(1) of the Act.

After any adjustments to the preliminary price are made under this section 60.3.4 of this memorandum, the result is the initial offer price.

60.4 Negotiation Process

In accordance with section 1191(b)(4) of the Act, and as described in section 40.1 of this memorandum, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into an Agreement, or, for initial price applicability year 2026, October 1,

2023. CMS intends to implement the offer and counteroffer process consistent with the requirements of the statute, with the goal of negotiating "the lowest maximum fair price for each selected drug" consistent with section 1194(b)(1) of the Act. In accordance with sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug for initial price applicability year 2026 no later than February 1, 2024. CMS plans to publish the Drug Price Negotiation Process Information Collection Request in Spring 2023 to capture information related to this process that will be submitted by the Primary Manufacturer.

After the written initial offer from CMS, the negotiation process would include:

(1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer from the Primary Manufacturer (if CMS' written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer;
(2) in accordance with Section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written counteroffer;
(3) if the Primary Manufacturer's written counteroffer is not accepted by CMS, up to three possible in-person or virtual negotiation meetings between the Primary Manufacturer and CMS;
(4) a final written offer made by CMS to the Primary Manufacturer; and,
(5) a response by the Primary Manufacturer to CMS' final written offer, either accepting or rejecting this final offer.

If at any point during the negotiation process, the Primary Manufacturer accepts CMS' latest written offer by signing the written offer, or CMS accepts the Primary Manufacturer's counteroffer by countersigning that written counteroffer, an agreement for the MFP would be reached. That MFP will apply for the selected drug for initial price applicability year 2026, but will be updated according to section 1195(b)(1)(A) of the Act. During the entire negotiation process, CMS cannot offer or agree to any manufacturer counteroffer that exceeds the statutorily determined ceiling price as defined in section 1194(c) of the Act and as described in section 60.2 of this memorandum.

60.4.1 Provision of an Initial Offer and Justification

In accordance with section 1194(b)(2)(B) of the Act, the written initial offer from CMS, made no later than February 1, 2024, must include a concise justification for the offer based on the factors described in section 50 of this memorandum. The concise justification for the offer would be based on the analysis described in section 60.3 of this memorandum. No offer can exceed the statutorily determined ceiling price as defined in section 1194(c) of the Act and as described in section 60.2 of this memorandum. CMS intends to provide the Primary Manufacturer with information about the statutorily determined ceiling price for the selected drug in its written initial offer to enable the Primary Manufacturer to better understand the context for the MFP offer made by the agency.

60.4.2 Required Components of a Counteroffer

In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will have no more than 30 days from receipt of the written initial offer from CMS to respond in writing by either accepting the initial offer for the selected drug or making a written counteroffer and providing a justification for such counteroffer based on the factors described in section 50 of this memorandum. Any counteroffer should also respond to the justification provided in CMS' written initial offer. The Primary Manufacturer's response should focus on the elements described in section 1194(e), and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the factors in section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS.

The Primary Manufacturer should provide a suggested MFP for the selected drug in its written counteroffer. As described in section 60.1 of this memorandum, the suggested MFP should be made consistent with the manner that CMS' initial written MFP offer was made; that is, a single price for the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. In accordance with section 1194(b)(2)(F) of the Act, CMS cannot accept a manufacturer written counteroffer that exceeds the statutorily determined ceiling price as defined in section 1194(c) of the Act and as described in section 60.2 of this memorandum.

The Primary Manufacturer may request that certain details contained in the offer or counteroffer be included in the public explanation for the agreed-upon MFP for the selected drug. CMS intends to consider this request when drafting the public explanation, which is discussed further in section 60.6.1 of this memorandum. In accordance with section 1195(a)(2) of the Act, CMS intends to publish the public explanation for the agreed-upon MFPs for selected drugs for initial price applicability year 2026 no later than March 1, 2025.

60.4.3 Negotiation Process After Manufacturer Counteroffer

In accordance with section 1194(b)(2)(D) of the Act, CMS will respond in writing to a written counteroffer made by the Primary Manufacturer. Though the statute does not specify a timeframe for the CMS response to the counteroffer, negotiations for initial price applicability year 2026 must end prior to August 1, 2024, i.e., an agreement on MFP for the selected drug must be reached no later than July 31, 2024.

In the case CMS' written initial offer is not accepted, and the Primary Manufacturer submits a written counteroffer, CMS intends to consider the counteroffer and either accept or reject it. If CMS's written response to the counteroffer rejects the Primary Manufacturer's written counteroffer, the agency will extend an invitation to the Primary Manufacturer for a negotiation meeting to take place within 30 days of CMS' receiving the manufacturer's written counteroffer. CMS intends to hold a minimum of one meeting between CMS and the Primary Manufacturer to discuss CMS' written initial offer, the Primary Manufacturer's written counteroffer, and factors considered. After this initial meeting, CMS intends to give each party (CMS and the Primary Manufacturer) the opportunity to request one additional meeting, resulting in a maximum of

three meetings between CMS and the Primary Manufacturer. These meetings may be conducted in-person at CMS headquarters or virtually.

These meetings for initial price applicability year 2026 would occur between the time the Primary Manufacturer's written counteroffer is submitted, which must be no later than 30 days after receipt of the written initial offer, and June 30, 2024. There would be approximately four months' time between the Primary Manufacturer's written counteroffer to CMS and the deadline for negotiation meetings to conclude. CMS intends to require all negotiation meetings end no later than June 30, 2024, to allow CMS sufficient time to prepare a final offer, send such offer to the manufacturer by July 15, 2024, and to allow the Primary Manufacturer time to consider such final offer and accept or reject the offer by July 31, 2024, as all negotiations must be concluded prior to August 1, 2024.

CMS believes that the negotiation meeting process described above allows for a more efficient and effective approach than preparing and exchanging additional written offers and counteroffers. Negotiation meetings would also allow both parties to discuss any new information that may have become available about the selected drug or its therapeutic alternatives, consistent with the factors described in section 1194(e)(2) of the Act, that may affect the determination of the MFP. Negotiation meetings would be attended solely by representatives of both the Primary Manufacturer and of CMS, and details discussed during these meetings would not be made public by either CMS or the Primary Manufacturer. In the public explanation of the MFP (as discussed in section 60.6.1 of this memorandum) and any other public documents discussing the MFP, CMS may make high-level comments on the data submitted or discussed in negotiation meetings, without sharing any proprietary information (as described in section 40.2.1 of this memorandum).

When developing this negotiation process, CMS considered using solely a written offer and counteroffer approach. That is, CMS considered providing one written offer and allowing a Primary Manufacturer to make a single written counteroffer, as described in the statute. CMS also contemplated allowing each party to make up to two written offers or counteroffers (i.e., CMS makes an initial offer, Primary Manufacturer possibly makes a counteroffer, CMS possibly makes a second offer, Primary Manufacturer possibly makes a second counteroffer). However, CMS believes that an offer/counteroffer process that includes in-person or virtual meetings would most effectively facilitate the negotiation process to arrive at an MFP and is more consistent with current industry practices for drug price negotiation. CMS solicits comments on the proposed drug price negotiation process described in this section 60.4.3. Specifically, CMS is seeking comment on the advantages and disadvantages of the negotiation process described above, as well as whether there are alternatives that CMS should consider beyond those described in this section 60.4.3.

60.4.4 Determination that Negotiations Have Finished

In accordance with section 1194(b)(2)(E) and 1191(d)(2)(B) of the Act, all negotiations between CMS and the manufacturer of the selected drug must end prior to a certain date. For initial price applicability year 2026, the date is August 1, 2024. In the event that negotiation meetings have

occurred, CMS intends to send the Primary Manufacturer a "Notification of Final Maximum Fair Price Offer" by July 15, 2024. This would serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. The Primary Manufacturer would be required to respond in writing to this final offer by either accepting or rejecting the offer by July 31, 2024. The following table details CMS' intended timing for the negotiation process for initial price applicability year 2026:

Date	**Milestone**
February 1, 2024	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer
30 days after receipt of written initial offer from CMS (March 2nd if the offer is made by CMS on February 1, 2024)	Statutory deadline for the Primary Manufacturer to accept the initial offer or submit a written counteroffer to CMS
30 days after receipt of the manufacturer counteroffer (April 1st if the manufacturer counteroffer is made on March 2, 2024)	Date by which CMS would provide a written response to manufacturer counteroffer
From the date that the Primary Manufacturer's written counteroffer is not accepted by CMS through June 30, 2024	Negotiation meetings (in-person or virtual, maximum of three possible meetings), if necessary CMS would schedule the first meeting to occur within 30 days of receiving the written counteroffer from the Primary Manufacturer
July 15, 2024	Date by which CMS would issue a "Notification of Final Maximum Fair Price Offer" to the Primary Manufacturer, if the written initial offer or written counteroffer were not accepted and negotiations progressed to negotiation meetings
July 31, 2024	Date by which the Primary Manufacturer would respond to (accept/reject) CMS' "Notification of Final Maximum Fair Price Offer," if applicable
July 31, 2024	Statutory deadline for all negotiations to end; CMS will notify the Primary Manufacturer of any failure to meet the deadline and the possible consequences thereof if no MFP agreement by July 31, 2024
August 1, 2024	Statutory end of negotiation period

60.5 Application of the MFP Across Dosage Forms and Strengths

An MFP that is agreed upon as described in section 60.4 of this memorandum establishes one price for the selected drug. In accordance with section 1196(a)(2) of the Act, CMS has the administrative duty to establish procedures to compute and apply the MFP across different dosage forms and strengths of the selected drug and not based on the specific formulation or package size or package type of such drug.

As described in section 60.1 of this memorandum, the MFP would reflect a single price for the selected drug per 30-day equivalent supply. In order to ensure that the MFP is made available to MFP-eligible individuals at the point of sale (and to pharmacies, mail order services, or other dispensers, with respect to such MFP-eligible individuals), however, CMS intends to publish the MFP at the per unit (e.g., tablet) level for each dosage form and strength associated with the selected drug.

The following methodology would take the single MFP across dosage forms and strengths for a 30-day equivalent supply and calculate an MFP per unit for each dosage form and strength of the selected drug. CMS seeks to use a methodology that scales the MFP per unit based on price differentials across dosage forms and strengths. CMS is considering using the wholesale acquisition cost (WAC) of the selected drug in this calculation (and is soliciting comment on this approach, as noted below). If WAC is used, the WAC per unit cost for each NDC-9 of the selected drug would first be converted to an amount per dosage form and strength, to account for scenarios in which there are multiple NDC-9s for a selected drug that share a dosage form and strength. The WAC per unit cost for each dosage form and strength would then be converted into an amount for a 30-day equivalent supply, so that the WAC would represent an equivalent amount to the negotiated single MFP. The WAC per 30-day equivalent supply would then be used to calculate a WAC price ratio for each dosage form and strength of the selected drug. The ratio derived from the WAC per 30-day equivalent supply for each dosage form and strength would then be multiplied by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each dosage form and strength of the selected drug. Lastly, to determine the per unit MFP for a dosage form and strength, CMS would convert from an MFP for a 30-day equivalent supply to an MFP per unit based on the average number of units in a 30-day equivalent supply.

The following steps provide additional detail behind the approach CMS is contemplating:

1. For each NDC-9 of the selected drug, CMS would divide the total number of units for the NDC-9 by the total number of units across all NDC-9s of that dosage form and strength using the Part D PDE data for 2022, then multiply that quotient by the WAC unit cost for that NDC-9.
    - Note: CMS is contemplating using the WAC unit cost for the period beginning January 1, 2022 and ending December 31, 2022 for purposes of this calculation to align with the time period of data used to calculate the ceiling for the MFP.
2. For each dosage form and strength of the selected drug, CMS would sum the amounts per NDC-9 from step 1 to yield a single WAC unit cost for that dosage form and strength of the selected drug.
3. For each dosage form and strength of the selected drug, CMS would divide the total number of units by the total 30-day equivalent supply calculated from Part D PDE data for 2022 to calculate the average number of units per 30-day equivalent supply.
4. For each dosage form and strength of each selected drug, CMS would multiply the WAC unit cost calculated in step 2 by the average number of units per 30-day equivalent supply calculated in step 3 to calculate the WAC per 30-day equivalent day supply.

5. For each dosage form and strength of the selected drug, CMS would divide the total 30-day equivalent supply for that dosage form and strength by the total 30-day equivalent supply across all dosage forms and strengths of the selected drug.
6. For each dosage form and strength of the selected drug, CMS would then multiply the amount calculated in step 5 by the WAC per 30-day equivalent supply as calculated in step 4.
7. CMS would then sum amounts calculated in step 6 across all dosage forms and strengths of the selected drug to calculate the WAC per 30-day equivalent supply across all dosage forms and strengths of the selected drug.
8. CMS would then divide the WAC per 30-day equivalent day supply for each dosage form and strength calculated in step 4 by the WAC per 30-day equivalent supply across dosage forms and strengths of the selected drug calculated in step 7, to calculate the WAC per 30-day equivalent supply ratio for each dosage form and strength of the selected drug.
9. For each dosage form and strength of the selected drug, CMS would multiply the single MFP for the selected drug by the relative WAC per 30-day equivalent supply ratio for that dosage form and strength calculated in step 8 to calculate the MFP per 30-day equivalent supply for that dosage form and strength.
10. CMS would divide the MFP per 30-day equivalent supply for each dosage form and strength of the selected drug calculated in step 9 by the quotient of the total number of units dispensed divided by the total 30-day equivalent supply to calculate the MFP per unit (e.g., tablet) for each dosage form and strength.

CMS intends to include the MFP per unit price for each dosage form and strength of the selected drug, calculated in step 10 of this section 60.5 of this memorandum, in the publication of MFPs, described in section 60.6 of this memorandum.

CMS is soliciting comment on this potential approach to computing the MFP across dosage forms and strengths of the selected drug. Specifically, CMS seeks comments on the advantages and disadvantages of using WAC in the computation of MFP at the per unit level. CMS seeks comments on any alternative approaches to the application of the MFP across dosage forms and strengths that could accurately and fairly compensate manufacturers and other entities throughout the supply chain. CMS also solicits comment on whether there are other approaches CMS should consider to apply the MFP across dosage forms and strengths that would be feasible, along with the disadvantages and advantages of the approaches. In particular, CMS would appreciate commenters' attention to the potential for disclosure of confidential or proprietary information (for example, manufacturer rebates) when considering other approaches.

60.5.1 Application of the MFP to New NDAs/BLAs or NDCs

Based on the definition of a qualifying single source drug described in section 30.1 of this memorandum, if the Primary Manufacturer for a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient after the drug has been selected, CMS intends to require that the MFP apply to drug or biological products marketed pursuant to the new NDA or BLA. Similarly, after the drug is selected, if the Primary Manufacturer for such drug receives approval or licensure for a new drug or biological product

or NDC that is marketed pursuant to a supplement to an existing NDA or BLA, CMS intends to require that the MFP apply to such new drug or biological product.

CMS is soliciting comment on how to compute the MFP for a drug or biological product or NDC that is a selected drug and is marketed for the first time, pursuant to an existing or new NDA or BLA, after the drug is selected and an MFP has been agreed.

60.6 Publication of the MFP

In accordance with section 1191(d)(6) of the Act, CMS will publish by September 1, 2024 the MFP for each drug selected for initial price applicability year 2026 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS intends to publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file (which would be updated annually to show the inflation-adjusted MFP for a selected drug), and the explanation for the MFP (published at a later date – see section 60.6.1 of this memorandum). CMS also intends to publish on the CMS website: (1) when a drug is no longer a selected drug and the reason for that change and (2) when an MFP between a Primary Manufacturer and CMS is not agreed upon.

60.6.1 Explanation for the MFP

Section 1195(a)(2) of the Act requires CMS to publish an explanation for the MFP no later than March 1 of the year prior to the initial price applicability year, which will be March 1, 2025 for initial price applicability year 2026. CMS intends for the published explanation to summarize how relevant negotiation factors from section 1194(e) of the Act were considered during the negotiation process. The explanation would focus on the factors that had the greatest influence in determining the MFP and include the other factors, as applicable. As described in section 40.2.1 of this memorandum, in this public explanation, CMS intends to make high-level comments on the data submitted to CMS, without sharing any proprietary information.

To the degree each of the following are applicable to the negotiation for a selected drug, the published explanation of an MFP would, at a minimum, list the selected drug, discuss contributing negotiation factors from section 1194(e) of the Act, and note any factors or circumstances that may be unique to the selected drug.

If an agreement for an MFP is not reached for a selected drug, neither an MFP nor an explanation of the MFP would be published. Instead, CMS would indicate on the website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug. In circumstances where an MFP is finalized after the statutory deadline for the conclusion of negotiations, the MFP and an accompanying explanation of the MFP would be posted in accordance with section 60.8 of this memorandum.

60.7 Exclusion from the Negotiation Process

In accordance with section 1192(c)(2) of the Act, CMS will not begin or will suspend (as applicable) the negotiation for a selected drug, with respect to an initial price applicability year, if CMS determines that at least one drug or biological product satisfies the following criteria: (1)

it is approved under section 505(j) of the FD&C Act with at least one dosage form and strength of the selected drug as the listed drug, or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product, and (2) is marketed pursuant to such approval or licensure. The approach CMS intends to take to make this determination is described in section 70 of this memorandum.

When the negotiation process is not started or is suspended, the selected drug will continue to be considered a selected drug with respect to such initial price applicability year (see section 70 of this memorandum for additional details).

60.8 Establishment of MFPs After the Negotiation Deadline

If the Primary Manufacturer of a selected drug would like to agree to an MFP after the end of the negotiation period, the Primary Manufacturer must notify CMS in writing that it would like to accept the last offer from CMS of an MFP, as reflected in the "Notification of Final Maximum Fair Price Offer."

In accordance with section 1195(b)(2) of the Act, in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, CMS shall publish the MFP no later than 30 days after the date such MFP is so determined. In accordance with section 60.6 of this memorandum, CMS will publish the MFP and an accompanying explanation on the CMS website.

70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

In accordance with section 1192(c) of the Act, a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations discussed below, if CMS determines (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure.

The approval (or licensure, as applicable) and marketing of an authorized generic drug (which includes authorized generic drugs and certain biological products as defined in section 1192(e)(2) of the Act) would not qualify as meeting the statutory requirement that a generic drug or a biosimilar biological product has been marketed. In accordance with section 1192(e)(2)(B)(i) of the Act, an authorized generic drug approved under section 505(t)(3) of the FD&C Act is treated as the same qualifying single source drug as a qualifying single source drug that is the listed drug, for the purposes of the Negotiation Program. Likewise, section 1192(e)(2)(B)(ii) of the Act indicates that the same rule applies to a biological product that is approved under section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under different labeling or packaging (other than

repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark.

Similar to the approach described in section 30.1 of this memorandum regarding how the agency determines whether a generic drug or biosimilar biological product is approved and marketed in order to identify qualifying single source drugs under section 1192(e) of the Act, for the purposes of determining whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list, CMS intends to review PDE data. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when these data reveal that the manufacturer of the generic drug or biosimilar biological product has engaged in bona fide marketing of that drug or product. CMS will monitor the manufacturers of generic drugs or biosimilar biological products to ensure they are engaging in bona fide marketing of the generic or biosimilar biological product (see section 90.4 of this memorandum for details).

Starting in October 2023, and repeated each month thereafter, CMS intends to take the following approach in determining whether the statutory criteria in 1192(c)(1)(B) of the Act for an approved generic drug or licensed biosimilar to be marketed pursuant to such approval or licensure is being met. CMS would use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar biological product has been approved or licensed for any strength(s) or dosage form(s) of the selected drugs for initial price applicability year 2026.

If CMS determines that a generic drug or biosimilar biological product has been approved or licensed, CMS would review the PDE data with dates of service during the most recent 12-month period available to determine if the manufacturer of the generic drug or biosimilar biological product has engaged in bona fide marketing of that drug or product. For example, when CMS performs this assessment in October of 2023, CMS intends to use PDE data with dates of service from October, 2022 through September, 2023. When CMS performs this assessment in November, 2023, CMS intends to use PDE data for dates of service from November, 2022 through October, 2023.

Per section 1192(c)(2) of the Act, if CMS makes a determination regarding generic drug or biosimilar biological product availability on or after the selected drug publication date, and before or during the negotiation period for an initial price applicability year, the selected drug will not be subject to the negotiation process for the negotiation period, and an MFP will not be established. Accordingly, for initial price applicability year 2026, if CMS makes this determination between September 1, 2023, and August 1, 2024, the drug will remain a selected drug through 2026, but no MFP will apply and the drug will not be replaced with another selected drug.

In accordance with section 1192(c)(1) of the Act, a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least 9 months after the date

on which CMS determines the statutory criteria in section 1192(c) are met. Accordingly, if CMS makes this determination between August 2, 2024, and March 31, 2026, for a drug selected for initial price applicability year 2026, then the drug will cease to be a selected drug on January 1, 2027, and the MFP will apply for 2026. If CMS makes this determination between April 1, 2026, and March 31, 2027, then the selected drug will cease to be a selected drug on January 1, 2028, and the MFP will apply for 2026 and 2027. These results are summarized in the following table:

Date on which CMS determines that a generic drug or biosimilar biological product is approved and marketed	**Result with respect to selected drug for the Negotiation Program**
September 1, 2023 through August 1, 2024 (which includes Negotiation Period for initial price applicability year 2026)	Selected drug remains a selected drug for initial price applicability year 2026, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2027.
August 2, 2024 through March 31, 2026	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026; selected drug ceases to be a selected drug on January 1, 2027.
April 1, 2026 through March 31, 2027	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026 and calendar year 2027; selected drug ceases to be a selected drug on January 1, 2028.

In all cases, after CMS determines the statutory criteria in section 1192(c) for generic competition are met for a selected drug, CMS intends to publish such information on the CMS website.

80. MFP Eligible Individuals

In accordance with section 1191(c)(2) of the Act, the term "maximum fair price eligible individual" means, with respect to a selected drug, the following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including enrollees in Employer Group Waiver Plans (EGWPs)) if coverage is provided under such plan for such selected drug; and/or in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under Medicare Part B, including an individual who is enrolled in an MA plan under Medicare Part C, if payment may be made under Part B for such selected drug.

90. Manufacturer Compliance and Oversight

In accordance with section 1196(b) of the Act, CMS intends to monitor compliance by a Primary Manufacturer with the terms of the Agreement and establish a mechanism through which violations of such terms shall be reported.

90.1 Monitoring of Manufacturer Compliance

CMS intends to closely monitor the Primary Manufacturer's compliance with the terms of the Agreement and other aspects of the Negotiation Program. Following the publication of selected drugs for each initial price applicability year, CMS intends to provide information about the negotiation process to the Primary Manufacturer of each selected drug (see section 40 of this memorandum for additional details). CMS anticipates this information will include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information. During the negotiation period, CMS plans to track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer. In addition, CMS intends to issue reminders and warning letters, as applicable, prior to various deadlines during the negotiation process.

Failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in excise tax liability (see section 90.3 of this memorandum).

As described in Section 100 of this memorandum, failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in civil monetary penalties (CMPs).

90.2 Monitoring of Access to the MFP

In accordance with section 1193(a)(3)(A) of the Act, under the Agreement with CMS with respect to a price applicability period, access to the MFP with respect to such a selected drug shall be provided by the Primary Manufacturer to MFP-eligible individuals at the pharmacy, mail order service, or other dispenser at the point of sale, and to the pharmacy, mail order service, or other dispenser with respect to such MFP-eligible individuals who are dispensed the selected drug.

Further, in accordance with section 1193(a)(5) of the Act, which requires that the manufacturer comply with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program, and section 40.4 of this memorandum, CMS intends to require that the Primary Manufacturer establish safeguards to ensure the MFP is available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers on units of the selected drug for which there are Secondary Manufacturers, as described in section 40.4 of this memorandum. CMS reiterates that the requirement to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as discussed in section 80 of this memorandum.

Moreover, in accordance with section 1196(a)(3)(A) of the Act, CMS intends to establish procedures for reporting violations related to access to the MFP with respect to MFP-eligible individuals who are enrolled in a PDP under Part D of title XVIII or MA-PD plan under Part C, as described later in this section.

Each component of the pharmaceutical supply chain may have a role in making the MFP available to MFP-eligible individuals, but it is ultimately the Primary Manufacturer's responsibility to ensure access to the MFP. There are various methods by which dispensing entities and MFP-eligible individuals can determine whether they are accessing the MFP for a selected drug.

For example, under section 1195(a) of the Act, the MFPs for selected drugs will be published by CMS, giving the public and other interested parties an opportunity to know the MFP for each selected drug, as well as the explanation for each MFP (see section 60.6 of memorandum for additional details). Under section 1191(d)(1), the MFPs for selected drugs for initial price applicability year 2026 must be published by September 1, 2024. In addition, CMS anticipates that pharmaceutical database companies will publish the MFPs such that they would become more readily accessible to pharmaceutical purchasers. CMS believes such transparency of the MFPs for selected drugs will help dispensing entities and MFP-eligible individuals to know the MFP for a selected drug and determine whether they are able to access the MFP. CMS is seeking comments on additional ways that CMS could help dispensing entities and MFP-eligible individuals know the MFP for a selected drug and determine whether they are able to access it.

Moreover, with respect to operationalizing access to the MFP, CMS intends to leverage existing mechanisms to ensure that dispensing entities have access to the MFP, and that the MFP for a selected drug is provided only to MFP-eligible individuals. For example, each Medicare Part D plan is required to use a unique Part D processor identification number (RxBIN) and Part D processor control number (RxPCN) combination to identify a Medicare Part D payer. This existing mechanism will ensure that the pharmacy is able to identify at the point of sale whether the individual is an MFP-eligible individual.

In addition, there is widespread use of chargeback payments and rebate mechanisms among the pharmaceutical stakeholders in the private sector, which allows for entities to receive rebates or discounts on their purchases after those purchases are made, based on the specific population to whom the drug or biological is dispensed. As appropriate, the private sector may make modifications to these existing mechanisms to effectuate access to the MFP.

For example, a pharmacy may purchase a medication for $100 per bottle and the MFP as applied to this selected package is $80. The Medicare beneficiary is enrolled in a Part D plan under which coverage of the selected drug is available, thus the beneficiary is an MFP-eligible individual. For this example, the plan has not negotiated a lower price for the medication. The pharmacy provides the negotiated price (i.e., MFP plus a dispensing fee) at the point of sale to the Medicare beneficiary. As a result of this transaction, the pharmacy is owed $20 by the manufacturer. The pharmacy would submit the information regarding the $20 chargeback amount to its wholesaler and receive a credit from the wholesaler for that amount. The wholesaler would be compensated by the manufacturer after billing the manufacturer for the chargeback amount.

CMS intends to establish a process by which beneficiaries, dispensing entities, and other providers and suppliers, would be able to report instances to CMS in which the MFP should have been made available to them but was not. CMS could establish a toll-free phone line and email box where an individual or a dispenser could communicate information to CMS regarding an incident in which the MFP was not provided. CMS anticipates the submissions would likely include the name of the individual reporting the incident, the nature of the incident, the date the incident occurred, the name and manufacturer of the drug, and contact information for follow-up.

Once received, CMS would review these email submissions, investigate reports of potential noncompliance, and if appropriate, impose CMPs on the Primary Manufacturer if CMS determines the Primary Manufacturer failed to provide an eligible dispenser access to the MFP for the selected drug, including in cases where there are one or more Secondary Manufacturers. CMS is seeking comment on how such a process would operate most effectively, including suggestions on ways that CMS could provide technical assistance to entities to ensure they are able to provide the MFP to MFP-eligible individuals and ways to ensure that MFP-eligible individuals whose cost-sharing was not consistent with MFP are made whole.

CMS would also expect manufacturers and other stakeholders to report instances in which a dispenser was not passing through the MFP to an MFP-eligible individual, or a dispenser was extending the MFP to non-MFP-eligible individuals.

CMS considered other options to ensure that manufacturers provide access to the MFP, but notes that the statute at section 1193(a)(3) of the Act specifies that it is the responsibility of the Primary Manufacturer, as part of its Agreement, to provide access to the MFP.

As discussed in section 40.4.1 of this memorandum and consistent with section 1193(d) of the Act regarding the manufacturer's Agreement with CMS, a manufacturer with an agreement with the Secretary under the 340B program is not required to provide a 340B covered entity with access to the MFP of a selected drug with respect to an MFP-eligible individual who is eligible to be furnished, administered, or dispensed such selected drug at the covered entity if the 340B ceiling price is lower than the MFP for such selected drug.

A manufacturer with an agreement with the Secretary under the 340B program is required to provide a 340B covered entity with access to the MFP of a selected drug with respect to an MFP-eligible individual who is eligible to be furnished, administered, or dispensed such selected drug at such covered entity if the MFP is below the 340B ceiling price for such selected drug.

Should it subsequently be determined that the 340B ceiling price is lower than the MFP for the selected drug, the manufacturer would have to provide to the covered entity the difference between the MFP and the 340B ceiling price. CMS intends to work with the Health Resources and Services Administration, which administers the 340B Drug Pricing Program, to help to ensure that the MFP is made available to 340B covered entities where appropriate.

CMS is seeking comments on other approaches the agency could consider that would be consistent with the statute to support the Primary Manufacturer in meeting its obligation to

ensure that any Secondary Manufacturer provides access to the MFP for dispensing entities. CMS is also aware that it is possible for an entity that meets the statutory definition of a manufacturer, but that is not the Primary Manufacturer or a Secondary Manufacturer, to market one or more drug or biological products pursuant to one or more NDA(s) or BLA(s) included in the selected drug.

For example, it is possible for an entity to purchase one or more drug or biological products included in the selected drug from a wholesaler, repackage or relabel such products, and then re-market them pursuant to one or more NDA(s) or BLA(s) included in the selected drug. CMS believes that the MFP should be made available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed units of the selected drug marketed by such manufacturers. CMS is soliciting comment on how it might monitor MFP access for these units of a selected drug, including how to identify the other manufacturers that market these selected drugs, and what mechanisms are available to ensure MFP is available for these units of the selected drug.

90.3 26 USC Section 5000D Excise Tax on Sale of Designated Drugs During Noncompliance Periods

The Internal Revenue Service (IRS) will administer the excise tax. The Treasury Department and the IRS anticipate issuing guidance separate from this document. As such, CMS is not soliciting comment on this section 90.3.

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

In accordance with section 1192(c) of the Act, a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations described in section 60.7 of this memorandum, if CMS determines (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure. Section 60.7 further describes the process by which CMS intends to determine whether a generic drug or biosimilar biological product is marketed. As described in section 30.1, CMS will review a generic drug's or biosimilar biological product's Total Expenditures under Part D as evidenced by PDE data in determining whether that drug or product has been marketed.

If CMS makes such a determination that a generic drug or biosimilar biological product has been marketed as evidenced by the PDE data, CMS intends to monitor whether robust and meaningful competition exists in the market once it makes such a determination, based on the process and timing described in section 60.7 of this memorandum. Examples of monitoring CMS may conduct include whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain, and whether it is available for purchase by community retail pharmacies in sufficient quantities from their

wholesale suppliers. In addition, CMS intends to analyze the share of generic drug or biosimilar biological product units identified in Part D PDE data as a percentage of total units of Part D expenditures.

CMS is seeking comment on the most effective ways to monitor whether robust and meaningful competition exists in the market after a selected drug ceases to be a selected drug.

100. Civil Monetary Penalties

In accordance with section 1197 of the Act, CMPs will be imposed on Primary Manufacturers of selected drugs that enter into an Agreement for (1) failure to ensure access to a price that is less than or equal to the MFP for MFP-eligible individuals and pharmacies, mail order services, and other dispensers who dispense the selected drug with respect to MFP-eligible individuals, (2) failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but has since undergone negotiation, as described in section 1192(f)(4) of the Act, and (3) violation of certain terms of the Agreement. In accordance with section 1197 of the Act, CMPs will be imposed on manufacturers for the provision of false information as described in section 100.3 below.

This memorandum addresses violations by a Primary Manufacturer with an Agreement in effect for failure to ensure access to a price for a selected drug less than or equal to the MFP, violation of terms of the Agreement, and provision of false information. Manufacturers will be subject to a CMP in accordance with section 1128A of the Act, described further in section 100.4 of this memorandum. Failure to pay a rebate for a biological product pursuant to section 1192(f)(4) of the Act will be addressed in future guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP

In accordance with section 1197(a) of the Act, CMS will impose a CMP on a Primary Manufacturer of a selected drug that has entered into an Agreement with CMS and fails to provide access to a price that is less than or equal to the MFP to MFP-eligible individuals dispensed the selected drug, to pharmacies, mail order services, or other dispensers with respect to MFP-eligible individuals who are dispensed the selected drug or to hospitals, physicians, or other providers or suppliers that furnish or administer the selected drug to MFP-eligible individuals.

For this violation, the statute provides for a CMP equal to 10 times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered (during such year) and the difference between the price for such drug made available (for such year by such manufacturer) to MFP-eligible individuals or a hospital, physician, or other provider or supplier that furnishes or administers the selected drug to an MFP-eligible individual and the MFP for such drug for such year. For the purposes of calculating this CMP, CMS intends to use the net price to acquire the drug for the pharmacy, mail service, or dispenser, not including any service fees, as the price made available for the selected drug. As discussed in section 40.4 of

this memorandum, CMS intends to monitor for compliance and audit, as needed, to ensure that the MFP or a price lower than the MFP is being made available for the selected drug.

100.2 Violations of the Agreement

Per section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Agreement with CMS under section 1193 of the Act that fails to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program pursuant to section 1193(a)(5) or fails to provide the information required under section 1193(a)(4) will be subject to a CMP of $1,000,000 for each day of such violation.

For example, as described in section 40.2 of this memorandum, information on each non-FAMP for the selected drug for the applicable period will be due to CMS as part of the forthcoming Negotiation Data Elements Information Collection Request no later than October 2, 2023 for initial price applicability year 2026. If the Primary Manufacturer fails to timely submit the required non-FAMP information, including the non-FAMP information for selected drug for which there is a Secondary Manufacturer, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the applicable submission deadline (e.g., October 3, 2023 for initial price applicability year 2026) as the first day of violation with each additional day of violation thereafter counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. Other examples of violations of the Agreement would include failure to comply with confidentiality requirements or data use and limitation requirements established in the Agreement.

Similarly, CMS will document requests for information required to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5). Such requests from CMS to the Primary Manufacturer will include a date by which any requested information must be submitted. Failure to provide requested information required to administer or monitor compliance with the Negotiation Program on or before the due date will result in a CMP. The first day of violation will be the day after the due date. For example, if CMS requests information for monitoring purposes by November 15, 2027, day one of the violation will be November 16, 2027. Each additional day of violation thereafter will be counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement.

A Primary Manufacturer that knowingly submits false information that is required under the Agreement, will be out of compliance with the requirement to submit information and will be subject to this CMP. In instances of a Primary Manufacturer knowingly submitting false information that is required under the Agreement, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day of submission of such false information under the Manufacturer Agreement, as the first day of violation with each additional day of violation thereafter counted until the day the Primary

Manufacturer provides a complete and accurate submission of the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement.

100.3 Provision of False Information

In accordance with section 1197(d) of the Act, if CMS determines that any manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) for the Small Biotech Exception, such manufacturer shall be subject to a CMP equal to $100,000,000 for each item of such false information. Likewise, if CMS determines that any Biosimilar Manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Biosimilar Delay, such manufacturer shall be subject to a CMP equal to $100,000,000 for each item of such false information.

100.4 Notice and Payment Procedures

For manufacturers that violate any of the provisions above, CMS will provide notice to the manufacturer with information regarding the CMP in accordance with section 1128A of the Act, including the option to either pay the CMP or to request a hearing as outlined in section 1128A. The CMP notice will include:

- Basis for the CMP;
- CMP amount due;
- Deadline for the manufacturer to respond with a hearing request or submit the CMP payment;
- Method to submit CMP payment(s); and
- Information on the right to request a hearing.

The manufacturer will have 60 days from the date of receipt of the CMP notice to request a hearing. The date of receipt is defined as the calendar day following the day on which the CMP notice is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act will apply. If the manufacturer does not request a hearing within 60 days, the CMP will be considered due on day 60 following the date of receipt of the CMP notice. As set forth in section 1128A(f), if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP funds will be deposited in accordance with section 1128A(f).

110. Part D Formulary Inclusion of Selected Drugs

In accordance with section 1860D-4(b)(3)(I) of the Act, Medicare Part D plans shall include each covered Part D drug that is a selected drug on Part D formularies during Contract Year (CY) 2026 and all subsequent years for which the MFP of the selected drug is in effect during the price applicability period.

120. Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs

This section of the memorandum describes the application of Medicare Part B and Part D inflation rebates to selected drugs. As background, Section 11101 of the IRA added a new section 1847A(i) to the Act to require that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Likewise, Section 11102 of the IRA added a new Section 1860D-14B to the Act, which requires that manufacturers of Part D rebatable drugs pay inflation rebates to Medicare for certain Part D rebatable drugs based on specific requirements and formulas.[37]

Given that Part B drugs are subject to the negotiation process starting in initial price applicability year 2028, this guidance describes the interaction between the Negotiation Program and the Part D inflation rebate program. CMS is soliciting comment, however, as to whether guidance would be appropriate or necessary with respect to the interaction between the Negotiation Program and the Part B inflation rebate program for years before initial price applicability year 2028.

The Part D drug inflation rebate program is applicable to certain Part D drugs that meet the definition of a Part D rebatable drug and are dispensed under Part D and covered and paid for by Part D plans beginning for each 12-month applicable period, beginning October 1, 2022. These rebates are paid by manufacturers to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

The Part B and Part D inflation rebate programs apply to selected drugs, regardless of the status of the drug as a selected drug. Alternatively said, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Part B and Part D inflation rebate programs. However, when a selected drug is no longer considered to be a selected drug, certain components of the applicable rebate amount formula are recalculated as discussed further below.

The statutory formula to determine the Part D drug inflation rebate amount owed by manufacturers for each Part D rebatable drug consists of various components, including the calculation of a benchmark period manufacturer price. This "benchmark period manufacturer price" is calculated based on a "payment amount benchmark period" for each Part D rebatable drug (established at section 1860D-14B(g)(3) for drugs first approved or licensed on or before October 1, 2021 and at section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021), and a "benchmark period CPI-U"[38] for each Part D rebatable drug (established at section 1860D-14B(g)(4) for drugs first approved or licensed on or before October 1, 2021 and section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021). The

[37] CMS published initial guidance on both Part B and Part D inflation rebates on February 9, 2023, which includes more specific details on the operation of the Part B and Part D inflation rebate programs. See: https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf and https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.
[38] CPI-U refers to the Consumer Price Index for all urban consumers (United States city average).

payment amount benchmark period is the basis for the calculation of the benchmark period manufacturer price.

For the period of time before a Part D rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part D inflation rebate amount, if applicable, based on the Part D rebatable drug's applicable payment amount benchmark period and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, the statute at section 1860D-14B(b)(5)(C) specifies a different "payment amount benchmark period" and a "benchmark period CPI-U" for each Part D rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period is reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the January of the last year beginning during such price applicability period.

Appendix A: Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026

Email subject line:

Biosimilar Delay: Notice of Intent to Submit Initial Delay Request for Initial Price Applicability Year 2026

Body of email:

Dear CMS,

I, an authorized representative of [insert manufacturer name], am notifying CMS that my company is the manufacturer of a biosimilar biological product and we anticipate the reference product for our biosimilar biological product will be included in a negotiation-eligible drug with respect to initial price applicability year 2026 for the Medicare Drug Price Negotiation Program. My company reasonably believes the market entry of our biosimilar biological product meets the criteria for the special rule to delay selection and negotiation of the negotiation-eligible drug, described in section 1192(f) of the Social Security Act. Therefore, I am notifying CMS of my company's intent to request that CMS delay the inclusion of the negotiation-eligible drug that includes the reference product for our biosimilar biological product on the selected drug list for initial price applicability year 2026.

As part of this notification, I am providing the following information:

My job title:	[insert]
My email address:	[insert]
My phone number:	[insert]
My company's mailing address:	[insert]
My company's biosimilar biological product name:	[insert]
Product name of the reference product for my company's biosimilar biological product	[insert]

Signed,
[Insert name of authorized representative]

Appendix B: Template for the Initial Delay Request Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act), to negotiate maximum fair prices (MFPs)[39] for selected drugs. Under section 1192(f) of the Act (the "Biosimilar Delay"), the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug (as defined in section 1192(d) of the Act) that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA for the Biosimilar that has been submitted for review by FDA.

Please refer to the memo titled "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" (Initial Negotiation Program Guidance) for additional details regarding the implementation of the Biosimilar Delay for initial price applicability year 2026. This form serves as the template that a Biosimilar Manufacturer may complete to submit an Initial Delay Request with respect to initial price applicability year 2026.

Submission of the email described in that memo indicating the Biosimilar Manufacturer's intention to submit an Initial Delay Request for initial price applicability year 2026 and receipt of the fillable Initial Delay Request form template and request-specific Box folder should occur prior to completing this form.

Instructions

- Initial Delay Requests that are incomplete or not timely submitted will not be accepted. For an Initial Delay Request to be timely for initial price applicability year 2026, the Biosimilar Manufacturer must submit a complete Initial Delay Request to CMS no later than 11:59 pm PT on May 22, 2023. CMS will deem an Initial Delay Request to be complete if it includes a complete Initial Delay Request form using this fillable template and the following documentation:
    - All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

[39] In accordance with section 1191(c)(3) of the Social Security Act, ("the Act"), maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

  - The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
  - Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.
- The data entry component of this submission should be completed by an individual authorized by the Biosimilar Manufacturer.
- The certification of the Initial Delay Request should be executed by (1) the chief executive officer (CEO) of the Biosimilar Manufacturer, (2) the chief financial officer (CFO) of the Biosimilar Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

CMS is relying on the fullness, accuracy, and completeness of the Biosimilar Manufacturer's submission to determine whether to approve the Initial Delay Request for initial price applicability year 2026. If the Biosimilar Manufacturer submits an Initial Delay Request that is not timely, complete, and accurate, the submission may adversely affect the Negotiation Program, including the process for selecting drugs for negotiation for initial price applicability year 2026.

Section 1: Identifying information

Identifying information for Biosimilar Manufacturer

Q1. Complete the following table with identifying information for the Biosimilar Manufacturer.

Field	Response
Entity Type	☐ Biosimilar Manufacturer
Entity name	Text
Employer Identification Number (EIN(s))	Text
Address	Text
Unique Identifier Assigned by CMS (P-number)	Text
Labeler Code(s)	Text

Identifying information on Biosimilar

Q2. Complete the following table with identifying information for the Biosimilar.

Field	Response
Product Name	Text
Active Ingredient	Text
NDC-9(s) (if applicable)	[optional, only if available]

Q3. List all applications for licensure for the Biosimilar under 351(k) of the Public Health Service (PHS) Act regardless of status (i.e., including applications that are approved, accepted for review, and submitted but not yet accepted for review). Leave approval date blank if license has not been approved.

Add additional rows for each application

Application Number	Submission Number	Application status	Approval Date [if licensed]	Indication	Dosage Form and Strength	Licensure planned before September 1, 2025?	Marketing planned before September 1, 2025?
nnnnnn	nnn	[Approved, Accepted for Review, Submitted]	MM/DD/YYYY	Text	Text	[Yes/No]	[Yes/No]

Identifying information on Reference Product

Q4. Complete the following table with identifying information for the reference product for the Biosimilar.

Field	Response
Product Name	Text
Active Ingredient	Text
NDC-9(s)	Text

Q5. List the Biologic License Application (BLA) approved by the Food and Drug Administration (FDA) under section 351(a) of the PHS Act for the reference product for the Biosimilar.

Application Number	Submission Number	Approval Date	Indication	Dosage Form and Strength	Sponsor
nnnnnn	nnn	MM/DD/YYYY	Text	Text	Text

Identifying information on Reference Manufacturer

Q6. Complete the following table with identifying information for the Reference Manufacturer.

Field	Response
Entity Type	☐ Reference Manufacturer
Entity name	Text
Employer Identification Number (EIN)	*[Optional, only if known]*
Address	*[Optional, only if known]*
Unique Identifier Assigned by CMS (P-number)	*[Optional, only if known]*
Labeler Code(s)	*[Optional, only if known]*

Section 2: Attestations to Requirements for Granting an Initial Delay Request

In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not delay inclusion of a biological product on the list of selected drugs if the Biosimilar Manufacturer meets any of the statutory criteria for an excluded manufacturer. Questions 7 through 9 address whether the Biosimilar Manufacturer is an excluded manufacturer.

Q7. Relationship between Biosimilar Manufacturer and Reference Manufacturer: In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not approve an Initial Delay Request if the Biosimilar Manufacturer is the same as the Reference Manufacturer or is treated as being the same as the Reference Manufacturer based on the aggregation rule in section 1192(f)(1)(C) of the Act. This aggregation rule provides, "all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer" for purposes of the Biosimilar Delay. Further, section 1192(f)(1)(C) of the Act establishes that "the term 'partnership' means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on" by two or more parties for the purposes of the Biosimilar Delay.

Read the following statement and check the box if accurate:

I confirm consistent with sections 1192(f)(1)(C) and 1192(f)(2)(D)(iv) of the Act that the Biosimilar Manufacturer submitting this request is not the same or is not treated as being the same as the Reference Manufacturer.	☐

Q8. Incentives: In accordance with section 1192(f)(2)(D)(iv)(II)(aa) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(aa) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that requires or incentivizes the Biosimilar Manufacturer to submit this or any other Initial Delay Request.	☐

Q9. Quantity Restriction: In accordance with section 1192(f)(2)(D)(iv)(II)(bb) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that restricts the quantity, either

directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(bb) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.	☐

In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025. Questions 10 and 11 are relevant for this determination.

Q10. Licensure: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed before September 1, 2025. For the purposes of this Initial Delay Request, 'licensed' means approved by the FDA under section 351(k) of the PHS Act.

Select the following option that best describes the current licensure status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the Biosimilar has been licensed.	☐
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the FDA has accepted such application for review.	☐
(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and has not received a determination from FDA that such application has been accepted for review.	☐
(D) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has not submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act.	☐

Q11. Marketing: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be marketed before September 1, 2025.

Select the following option that best describes the current marketing status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar is currently marketed.	☐
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed but the Biosimilar Manufacturer expects it to be marketed by September 1, 2025.	☐
(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed and the Biosimilar Manufacturer does not expect it to be marketed by September 1, 2025.	☐

Section 3: Supporting Documentation

Q12. Manufacturing schedule: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, the manufacturing schedule for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation - Manufacturing schedule' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload the manufacturing schedule(s) for the Biosimilar submitted to the FDA for each application listed in Q3.

Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure is available for submission.	☐
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure.	☐

Q13. Disclosures: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Disclosures' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such disclosures.

Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, are available for submission.	☐
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all such disclosures.	☐

Q14. Agreements:
In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Agreements' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such agreements.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.	☐

Section 4: Certification

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including to determine whether CMS should delay the selection of a biological product that would, absent this request, be included on the selected drug list for initial price applicability year 2026, as described in section 1192(f) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes []
No []

Contact Information

Field	Response
Name of the Person Responsible for the Submission	Text
Title	Text
Telephone	Text
Email	Text
Signature	Text
Date	Text

Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

For the purposes of describing the data at sections 1194(e)(1) and 1193(a)(4)(A) of the Act to be collected for use in the Negotiation Program, as described in section 50.1 of this memorandum, CMS intends to adopt the following definitions as described in this Appendix C. CMS is seeking comment on this Appendix C.

General

- "Marketing" is defined as the introduction or delivery for introduction into interstate commerce of a drug product.
- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment. If a Primary Manufacturer uses a cost of capital below 8.1 percent, that amount should be used.

Non-FAMP

For the purposes of collecting the data described in section 1193(a)(4)(A) of the Act for use in the Negotiation Program, as described in section 50.1.1 of this memorandum, CMS intends to adopt the following definitions:

- Non-FAMP price: Section 1194(c)(6) of the Act defines "average non-Federal average manufacturer price" as the average of the non-FAMP (as defined in section 8126(h)(5) of title 38 of the U.S. Code) for the four calendar quarters of the year involved.
- Non-FAMP unit: Non-FAMP unit is the package unit as described in section 8126(h)(6) of title 38 of the U.S. Code.

Research & Development (R&D) Costs

For the purposes of describing R&D costs of the Primary Manufacturer to be collected for use in the Negotiation Program for the selected drug and the extent to which the Primary Manufacturer has recouped those costs, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

CMS is considering R&D costs to mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications of a drug falling into the following categories, and excluding Federal funding, acquisition costs, and costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Basic Pre-Clinical Research Costs
2. R&D: Post-Investigational New Drug (IND) Application Costs
3. R&D: Completed U.S. Food and Drug Administration (FDA)-Required Phase IV Trials
4. R&D: Post-Marketing Trials
5. R&D: Abandoned and Failed Drug Costs
6. R&D: All Other R&D Costs

CMS is calculating recoupment of R&D costs using the global, total lifetime net revenue for the selected drug:

7. Recoupment: Global, Total Lifetime Net Revenue for the Selected Drug.

The definitions and associated time periods for these terms are included below.

Definitions for 1. R&D: Basic Pre-Clinical Research Costs:

- Basic pre-clinical research is defined as all discovery and preclinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and is the sum of (1) direct research expenses and (2) a proportion of indirect research expenses.
- The basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA/BLA(s) or NDA/BLA(s) of the future selected drug (whichever is earlier) to the day before the last IND application for the selected drug went into effect.[40, 41] This may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications approved, use the date of the first IND application that went into effect as the end date for the 52-month period.[42]
- Direct research expenses are costs that can be specifically attributed to the discovery and preclinical development of the selected drug. Direct research expenses could include personnel (compensation for investigators and staff) researching the selected drug, materials for conducting basic preclinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect research expenses and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[43] For example, if the *direct* costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then

[40] CMS acknowledges that the exact date of initial discovery might not be known, but manufacturers should use their best estimate.

[41] For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the NDA(s)/BLA(s) of the selected drug, use the earliest date of acquisition for any NDA/BLA of the selected drug.

[42] DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. Journal of Health Economics. https://fds.duke.edu/db?attachment-25--1301-view-168. CMS believes that 52 months represents an average across studies. For example, the Congressional Budget Office (CBO) estimated that the preclinical phase can take anywhere from 31 months to 84 months in this report: https://www.cbo.gov/publication/57126.

[43] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA.* 2020;323(9):844–853. doi:10.1001/jama.2020.1166; Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html.

indirect costs should be allocated proportionally, thus for the selected drug they should be 10 percent of the total spending on *indirect* costs during that time period.

Definitions for 2. Post-Investigational New Drug (IND) Application Costs

- Post-IND costs are defined as all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication.
- Direct costs for post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period.
- The post-IND period is defined as the day the IND went into effect for the first FDA-approved indication for the selected drug through the date the most recent NDA/BLA was approved for the selected drug.

Definitions for 3. R&D: Completed U.S. Food and Drug Administration (FDA)-Required Phase IV Trials

- Post-marketing trials are defined as studies conducted after the FDA has approved a product for marketing, including studies required of or agreed to by a manufacturer.
- Direct costs for completed Phase IV studies include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed Phase IV study.

Definitions for 4. R&D: Post-Marketing Trials

- Post-marketing trials are defined as studies conducted after the FDA has approved a product for marketing, including studies required of or agreed to by a manufacturer.
- The post-marketing trial costs should include the direct cost for FDA-required Phase IV trials that were not completed and the direct cost for post-marketing trials conducted for the purposes of marketing claims.
- Direct costs include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the incomplete Phase IV trial or the post-marketing trial.

Definitions for 5. R&D: Abandoned and Failed Drug Costs

- Failed or abandoned product costs include a sum of the portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
- Failed or abandoned products costs include a portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials.
    - Direct research expenses are costs that can specifically be attributed to the discovery and preclinical development of the drug.

  - Direct research expenses include personnel (compensation for investigators and staff) researching the drug, materials for conducting basic preclinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned products costs include a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
  - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
  - Direct post-IND costs include Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting dosing and clinical trials for the drug.

Definitions for 6. R&D: All Other R&D Costs

- No additional definitions adopted.

Definitions for 7. Global, Total Lifetime Manufacturer Net Revenue for the Selected Drug

- CMS will use the Primary Manufacturer's global, total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.
- Global, total lifetime net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
- Global, total lifetime net revenue period is defined as the date the drug or biologic was first sold anywhere globally through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Current Unit Costs of Production and Distribution

For the purposes of describing current unit costs of production and distribution to be collected for use in the Negotiation Program for the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- In accordance with section 1191(c)(6) of the Act, the term 'unit' means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)[44]: each (EA), milliliter (ML), or gram (GM). The unit reported must be specified for each of the NDC-9s included in the selected drug. Selections of EA, ML or GM must be made as follows:
    - "EA" is used when the product is dispensed in discrete units. These products are not measured by volume or weight. The Billing Unit of "EA" is also used to address exceptions where "GM" and "ML" are not applicable. Examples of products defined as "EA" include, but are not limited to:
        - Tablets;
        - Capsules;
        - Suppositories;
        - Transdermal patches;
        - Non-filled syringes;
        - Tapes;
        - Devices/Digital Therapies;
        - Blister packs;
        - Oral powder packets;
        - Powder filled vials for injection;
        - Kits; and
        - Unit-of-use packages of products other than injectables with a quantity less than one milliliter or gram should be billed as "one each," for example, ointment in packets of less than 1 gram or eye drops in dropperettes that contain less than 1 mL.
    - "ML" is used when a product is measured by its liquid volume. Examples of products defined as "ML" include, but are not limited to:
        - Liquid non-injectable products of 1 mL or greater;
        - Liquid injectable products in vials/ampules/syringes;
        - Reconstitutable non-injectable products at the final volume after reconstitution except when they are in powder packets; and
        - Inhalers (when labeled as milliliters on the product).
    - "GM" is used when a product is measured by its weight. Examples of products defined as "GM" include, but are not limited to:
        - Creams (of 1 GM or greater);
        - Ointments (of 1 GM or greater); and
        - Inhalers (when labeled as GM on the product)[45].
- Costs of production are defined as all (direct and allocation of indirect) costs related to:
    - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
    - Formulation and preparation of the finished drug product;

[44] https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22

[45] https://standards.ncpdp.org/Standards/media/pdf/BUS_fact_sheet.pdf . *Permission is hereby granted to any organization to copy and distribute this material as long as this copyright statement is included, the contents are not changed, and the copies are not sold.*

  - Quality control and testing of the drug; and
  - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug;
- Costs of distribution are defined as all (direct and allocation of indirect) costs related to:
  - Packaging and packaging materials;
  - Labeling;
  - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
  - Operating costs for facilities, transportation, and other expenses related to packaging, labelling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer;
- Current unit costs of production and distribution of the selected drug are defined to include:
  - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
  - Average unit costs during the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year);
  - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.; and
  - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third parties (e.g., contractors) performing activities that qualify as production or distribution, as specified above.
  - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-9 based on unit volume.
- Current unit costs of production and distribution of the selected drug are defined not to include:
  - R&D costs; and
  - Marketing costs.

Prior Federal Financial Support

For the purposes of describing prior federal financial support for novel therapeutic discovery and development to be collected for use in the Negotiation Program with respect to the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, and any other funds provided by the

federal government that support discovery, research, and/or development related to the selected drug.

- "*Prior* Federal financial support" refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, to the day through the date the most recent NDA/BLA was approved for the selected drug.

Patents, Exclusivities, and Approvals

For the purposes of describing patents, exclusivities, and approvals to be collected for use in the Negotiation Program for the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- CMS considers patents relevant to this data to include:
  - all pending and approved patent applications, including expired and non-expired approved patents, submitted, sponsored, licensed, and/or acquired by the Primary Manufacturer relating to the selected drug as of September 1, 2023;
  - patents linked to the selected drug where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product); and
  - all patent applications, pending and approved, for which a claim of patent infringement could reasonably be, or has been, asserted against a person engaged in the unlicensed manufacture, use, or sale of the selected drug in any form.
- A pending patent application is any provisional or nonprovisional patent application submitted to the United States Patent and Trademark Office for which a patent number(s) has not been issued.
- An approved patent application is any patent application submitted to the United States Patent and Trademark Office for which a patent number(s) has been issued.
- An expired patent is any patent application approved by the United States Patent and Trademark Office for which a patent number(s) was issued and that has now expired.
- Exclusivity periods recognized by FDA refer to certain delays and prohibitions on the approval of competitor drugs that attach upon approval of a drug. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met.[46] Exclusivities include:
  - Orphan Drug Exclusivity (ODE);[47]
  - New Chemical Entity Exclusivity (NCE);[48]
  - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[49]

[46] https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity
[47] 21 C.F.R. 316.31, 316.34
[48] 21 C.F.R. 314.108
[49] Section 505E of the Federal Food, Drug, and Cosmetic Act

  - New Clinical Investigation Exclusivity (NCI);[50]
  - Pediatric Exclusivity (PED);[51] and
  - Reference Product Exclusivity for Biological Products.[52]
- Active and pending FDA applications and approvals includes:
  - all applications for approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or sections 351(a) of the Public Health Service Act, including those not yet decided; and
  - all applications for which the Primary Manufacturer is directly or indirectly involved in the production, preparation, propagation, compounding, conversion, processing, packaging, repackaging, labeling, relabeling, or distribution (not just those applications the Primary Manufacturer has submitted or sponsored).

Market Data and Revenue and Sales Volume Data

For the purposes of describing market data and revenue and sales volume data to be collected for use in the Negotiation Program for the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this memorandum, CMS intends to adopt the definitions described in this subsection.

- Wholesale acquisition cost (WAC) unit price: The manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price would be reported at the NDC-9 level.
- National Council of Prescription Drug Programs Billing Unit Standards: The three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)[53] are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data that also uses the NCPDP BUS.
- 340B ceiling price: The 340B ceiling price is defined in section 340B(a)(1) of the PHS Act and in 42 CFR §10.3 and §10.10(a). The 340B ceiling price would be reported at the NDC-11 level.
- Medicaid best price: The Medicaid best price is defined in 42 CFR §447.505(a). The Medicaid best price would be reported at the NDC-9 level.
- Average manufacturer price (AMP) unit: The type of unit used to report AMP (42 CFR §447.504) and best price (42 CFR §447.505) to Medicaid: injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie.

[50] 21 C.F.R. 314.108
[51] Section 505A of the Federal Food, Drug, and Cosmetic Act
[52] Section 351(a) of the PHS Act
[53] https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22

- 340B prime vendor program (PVP) price: The price offered under the 340B PVP established by section 340B(a)(8) of the PHS Act. The 340B PVP price would be reported at the NDC-11 level.
- Federal supply schedule (FSS) price: The price offered by the Department of Veterans Affairs (VA) in its FSS program, by delegated authority of the General Services Administration.[54] The FSS price would be reported at the NDC-11 level.
- Big Four price: The Big Four price is described in section 8126 of title 38, U. S. C. The Big Four price would be reported at the NDC-11 level.
- U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid Managed Care. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price would be reported at the NDC-9 level.
- U.S. commercial average net unit price─ without patient assistant program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price net of coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price─ without patient assistant program would be reported at the NDC-9 level.
- U.S. commercial average net unit price─ best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price─ best would be reported at the NDC-9 level.
- Manufacturer average net unit price to Part D Plan sponsors: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for Part D plan sponsors. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The manufacturer average net unit price to Part D Plan sponsors would be reported at the NDC-9 level.

[54] https://www.fss.va.gov/index.asp

- Manufacturer average net unit price to Part D Plan sponsors─ without patient assistant program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer average net unit price to Part D Plan sponsors net of coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The manufacturer average net unit price to Part D Plan sponsors─ without patient assistant program would be reported at the NDC-9 level.
- Manufacturer average net unit price to Part D Plan sponsors─ best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest manufacturer average net unit price to Part D Plan sponsors offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any Part D plan sponsor. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The manufacturer average net unit price to Part D Plan sponsors─ best would be reported at the NDC-9 level.
- Covered entity: Covered entity is defined in 42 CFR §10.3.
- Acquisition: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the Primary Manufacturer purchase of the rights to hold previously approved or future NDA(s)/BLA(s) of the future selected drug from another manufacturer.
- Gross revenue: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the Primary Manufacturer and all Secondary Manufacturer(s) total sales to all purchasers in the U.S. Gross revenue would be reported at the NDC-9 level.
- Net revenue: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, gross revenue minus discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers in the U.S. Net revenue would be reported at the NDC-9 level.
- Net revenue─ without patient assistance programs: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, net revenue further net coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). Net revenue─ without patient assistance programs would be reported at the NDC-9 level.
- Quarterly total U.S. unit volume: The total number of units (using NCPDP BUS) of the selected drug sold to any purchaser during the quarter. Quarterly total U.S. unit volume would be reported at the NDC-9 level.

EXHIBIT D

Drugs likely subject to Medicare negotiation, 2026-2028

Sean Dickson, JD, MPH; Inmaculada Hernandez, PharmD, PhD

Plain language summary

By 2028, Medicare will negotiate prices for 38 drugs dispensed in pharmacies and 2 drugs provided in physician offices. Medicare drug price negotiation will benefit patients with common diseases such as diabetes, cancer, respiratory conditions, or cardiovascular disease. Our list of drugs expected to be negotiated by Medicare shows patients, clinicians, and insurers which drugs will become more affordable for seniors in the next few years.

Implications for managed care pharmacy

Our list informs health plans of the drugs that will likely see major reductions in price and subsequently cost sharing under Medicare and identifies other top-spend drugs that will be ineligible for negotiation. This information will guide Part D benefit design, formulary placement, and insurer negotiations with manufacturers for discounts.

Author affiliations

West Health Policy Center, Washington, DC (Dickson); Division of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California, San Diego, La Jolla (Hernandez).

AUTHOR CORRESPONDENCE:
Inmaculada Hernandez, 1.858.822.6047;
inhernandez@health.ucsd.edu

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ABSTRACT

BACKGROUND: After the passage of the Inflation Reduction Act, Medicare will be able to negotiate drug prices starting in 2026. The Congressional Budget Office has estimated the total savings achieved each year for negotiation but has not publicly identified the drugs anticipated to be negotiated each year.

OBJECTIVE: To identify the drugs expected to be negotiated by Medicare in 2026-2028.

METHODS: We identify drugs expected to be negotiated by the Centers for Medicare & Medicaid Services in 2026-2028 based on the statutory criteria, Part B and Part D gross spending in 2020, and estimates of when a drug will be subject to generic or biosimilar competition. We also identify the reasons why other high-spend drugs will be ineligible for negotiation.

RESULTS: In 2026-2028, we estimate that Medicare will negotiate prices for 38 Medicare Part D drugs and 2 Part B drugs. Combined, the 40 products eligible for negotiation in 2026-2028 accounted for $67.4 billion in gross Medicare spending in 2020. Part D drugs eligible for negotiation in 2026-2028 include 7 inhalers, 8 antidiabetics, 5 kinase inhibitors, and 3 oral anticoagulants. In all but 5 cases, high-spend drugs ineligible for negotiation were disqualified because of generic or biosimilar competition.

CONCLUSIONS: Medicare drug price negotiation has the potential to benefit Medicare beneficiaries across some of the most common disease states. By generating the list of drugs likely subject to Medicare negotiation in the initial years, we hope to provider researchers, policymakers, prescribers, and patient advocates with expectations on which drugs are expected to see reductions in beneficiary cost sharing.

Nearly 20 years after the creation of the Medicare Part D program, the Centers for Medicare & Medicaid Services (CMS) will be able to negotiate drug prices directly with manufacturers following the passage of the Inflation Reduction Act of 2022.[1] Under this new authority, CMS will apply negotiated maximum fair prices for selected small-molecule drugs that have been on the market for at least 9 years and for biologic therapies marketed for more than 13 years, although the negotiations begin 2 years before they are applied, making the age threshold 7 and 11 years, respectively. Drugs are only eligible if there is no marketed generic or biosimilar

therapy, excluding authorized generics or authorized biosimilars. Drugs approved under an orphan drug application and that only have orphan indications for a single disease or condition will be ineligible for negotiation. Orphan drugs with indications for multiple diseases will, however, remain eligible for negotiation. CMS will negotiate prices on the highest gross spend 10 Part D drugs for implementation in 2026, 15 Part D drugs for 2027, and 15 drugs from across the Medicare Part B and D programs for 2028 (Medicare Part B covers provider-administered drugs, whereas Part D covers retail prescription drugs). From 2029 onward, 20 drugs from across the 2 Parts will be negotiated. In calculating gross spend, CMS includes dispensing fees for Part D drugs and add-on and bundled payments for Part B drugs.

Negotiated prices will remain in effect until the drug becomes ineligible because of generic or biosimilar competition, and the negotiated price will be capped at a certain discount based on the drug's age. Drugs marketed for 9-12 years will be subject to a minimum discount of 25%; drugs marketed 12-16 years face a minimum discount of 35%; and drugs marketed for more than 16 years must discount prices by at least 60%; however, prior to 2030, drugs marketed 12-16 years will only be subject to the 25% minimum discount. Drugs will become ineligible for negotiation when a generic or biosimilar version has been approved and marketed for at least 9 months prior to January 1 of the year in which negotiated prices would apply. The definition of generic or biosimilar marketing status relies on the determination of the US Food and Drug Administration (FDA).[2]

Two years prior to the implementation of negotiated prices, CMS will begin negotiation on the top eligible drugs based on age and generic/biosimilar availability by gross spend, although negotiation for 2026 will begin in 2023 under a timeline provided by CMS.[3] The Congressional Budget Office (CBO) has estimated the total savings achieved each year for negotiation (in 2026, $3.7 billion; 2027, $8.3 billion; 2028, $17.5 billion)[4] but has not publicly identified the drugs anticipated to be negotiated each year. To aid policymakers and practitioners, we leverage public data to project which specific drugs will likely be subject to negotiation from 2026-2028.

Methods

We identify drugs expected to be negotiated by CMS for benefit years 2026-2028 based on drug age, drug or biologic status, orphan drug status, Part B and Part D gross spending in 2020,[5,6] and estimates of when a drug will be subject to generic or biosimilar competition (loss of exclusivity [LOE]). Drug age, drug or biologic status, and orphan drug status were ascertained from the FDA website.[7] Part B and Part D gross spending in 2020 was obtained from the CMS spending dashboards, which report gross spending per product (inclusive of manufacturer discounts).[4,5] For drug products, we estimated LOE based on the latest expiration date of any drug substance or drug product patent listed in the Orange Book;[8] this was superseded by any publicly disclosed patent settlement date, for which we performed an online search for each product and generic or biosimilar competitors, as appropriate, and reviewed the most recent annual securities filings from each manufacturer. For biologics, we use estimated LOE from an expert report.[9] Notably, for a drug to be ineligible for negotiation because of competition, the generic or biosimilar must have been marketed at least 9 months prior to the year of implementation of negotiated prices. In other words, a reference drug with generic entry in June 2026 would remain eligible for negotiation until 2028.

In addition to our projections of drugs subject to negotiation, we report public information on the minimum discount percentage required by statute based on the drug's years on the market, Medicare gross spending on the drug in 2020 obtained from the dashboards,[5,10] and the CBO's estimated annual savings from negotiation.[4] Finally, we report all high-spend drugs that we excluded from the list of likely negotiated drugs and the reasons for exclusion.

Additional information: The study was not registered.

Results

For 2026, the top drugs projected for negotiation include anticoagulants Eliquis (apixaban) and Xarelto (rivaroxaban), oral antidiabetics Januvia (sitagliptin) and Jardiance (empagliflozin), the tumor necrosis factor inhibitor Enbrel (etanercept), and the inhalers Symbicort (budenoside/formoterol) and Breo Ellipta (fluticasone/vilanterol) (Table 1). Three cancer therapies are projected to be eligible for negotiation in 2026 as well, including the kinase inhibitors Imbruvica (ibrutinib) and Ibrance (palbociclib) and the antiandrogen Xtandi (enzalutamide). In 2020, these 10 products accounted for $33.7 billion (17%) of Part D gross spending.

Based on their rank by gross spending, drugs likely to be negotiated for 2027 include 4 inhalers, 3 antidiabetics, 2 kinase inhibitors, the antipsychotic Invega Sustenna (paliperidone), the hepatitis C treatment Epclusa (sofosbuvir/velpatasvir), the irritable bowel syndrome therapy Linzess (linaclotide), the pancreatic enzyme mix Creon, the antibiotic Xifaxan (rixafimin), and the tardive dyskinesia therapy Ingrezza (valbenazine). The 15 products projected to be negotiated for 2027 accounted for $16.4 billion (8.3%) in gross Part D spending in 2020.

TABLE 1 Drugs Anticipated to Face Medicare Price Negotiation, 2026-2028

Rank/part		Brand name	Generic name	Manufacturer	Spending in 2020[a], $	Years since approval[b]	Expected loss of exclusivity[c] (by year)	Minimum discount[d], %	CBO-estimated annual savings[e], $
Subject to negotiation in 2026									
1	D	Eliquis	Apixaban	BMS/Pfizer	9,936,069,814	13.0	2028	25	3.7 billion
2	D	Xarelto	Rivaroxaban	Janssen Pharm.	4,701,314,805	14.5	2027	25	
3	D	Januvia[f]	Sitagliptin phosphate	Merck Sharp & D	3,865,087,773	19.2	2026	60	
4	D	Imbruvica	Ibrutinib	Pharmacyclics	2,962,909,304	12.1	2033	25	
5	D	Jardiance	Empagliflozin	Boehringer Ing.	2,376,166,292	11.4	2028	25	
6	D	Enbrel	Etanercept	Amgen	2,154,714,778	27.2	2029	60	
7	D	Symbicort	Budesonide/formoterol	Astrazeneca	2,135,408,250	19.5	2028	60	
8	D	Ibrance	Palbociclib	Pfizer US Pharm	2,108,937,188	10.9	2034	25	
9	D	Xtandi	Enzalutamide	Astellas Pharma	1,968,567,948	13.4	2027	25	
10	D	Breo Ellipta	Fluticasone/vilanterol	Glaxosmithkline	1,504,155,910	12.7	2030	25	
Total 2026 drugs					**33,713,332,062**				
Subject to negotiation in 2027									
1	D	Trelegy Ellipta	Fluticasone/ umeclidinium/vilanterol	Glaxosmithkline	1,487,802,308	9.3	2027	25	8.3 billion (2027 savings from drugs negotiated in 2026-2027)
2	D	Ozempic	Semaglutide	Novo Nordisk	1,455,812,267	9.1	2031	25	
3	D	Invega Sustenna	Paliperidone palmitate	Janssen Pharm.	1,372,610,289	17.4	2031	60	
4	D	Jakafi	Ruxolitinib	Incyte Corporat	1,296,674,522	15.1	2028	25	
5	D	Tradjenta	Linagliptin	Boehringer Ing.	1,288,663,293	15.7	2027	25	
6	D	Ofev	Nintedanib esylate	Boehringer Ing.	1,157,563,828	12.2	2029	25	
7	D	Spiriva[g]	Tiotropium bromide	Boehringer Ing.	1,153,453,863	22.9	2030	60	
8	D	Linzess	Linaclotide	Allergan Inc.	1,144,468,128	14.4	2033	25	
9	D	Anoro Ellipta	Umeclidinium/vilanterol	Glaxosmithkline	1,002,343,776	13.1	2030	25	
10	D	Creon	Lipase/protease/amylase	Abbvie US LLC	960,235,542	17.8	2031	60	
11	D	Epclusa	Sofosbuvir/velpatasvir	Gilead Sciences	867,053,907	10.5	2034	25	
12	D	Xifaxan	Rifaximin	Salix Pharmaceu	844,562,189	22.6	2027	60	
13	D	Spiriva Respimat[g]	Tiotropium bromide	Boehringer Ing.	804,565,194	12.3	2030	25	
14	D	Ingrezza	Valbenazine tosylate	Neurocrine Bios	792,681,813	9.7	2038	25	
15	D	Janumet	Sitagliptin phos/ metformin hcl	Merck Sharp & D	791,886,114	19.7	2026	60	
Total 2027 drugs					**16,420,377,033**				

continued on next page

For 2028, Part B drugs will become eligible for negotiation. However, only 2 Part B products are projected to be subject to negotiation (Keytruda [pembrolizumab] and Opdivo [nivolumab]), as most high-spend Part B drugs will face biosimilar competition by then (Table 2). Given the 2 Part B products, 13 Part D products are projected to be subject to price negotiation for 2028, including 3 antidiabetics and 4 HIV treatments. The 15 products projected to be negotiated for 2028 accounted for $17.2 billion (8.7%) in gross Medicare spending in 2020. Combined, the 40

TABLE 1 **Drugs Anticipated to Face Medicare Price Negotiation, 2026-2028** *(continued)*

Rank/part		Brand name	Generic name	Manufacturer	Spending in 2020[a], $	Years since approval[b]	Expected loss of exclusivity[c] (by year)	Minimum discount[d], %	CBO-estimated annual savings[e], $
Subject to negotiation in 2028									
1	B	Keytruda	Pembrolizumab	Merck Sharp & D	3,500,947,569	13.3	2028	25	17.5 billion (2028 savings from drugs negotiated in 2026-2028)
2	D	Trulicity[h]	Dulaglutide	Eli Lilly & Co.	3,284,873,062	13.3	2027	25	
3	B	Opdivo	Nivolumab	BMS	1,586,591,103	13.0	2028	25	
4	D	Biktarvy	Bictegravir/ emtricitabine/tenofovir	Gilead Sciences	1,775,846,507	9.9	2036	25	
5	D	Genvoya	Elvitegravir/cobicistat/ emtricitabine/tenofovir	Gilead Sciences	755,819,244	12.2	2032	25	
6	D	Triumeq	Abacavir/dolutegravir/ lamivudine	Viiv Healthcare	738,986,222	13.4	2029	25	
7	D	Farxiga	Dapagliflozin	Astrazeneca	736,787,564	14.0	2030	25	
8	D	Tivicay	Dolutegravir	Viiv Healthcare	656,037,862	14.4	2029	25	
9	D	Lumigan[h]	Bimatoprost	Allergan Inc.	633,540,096	17.4	2027	60	
10	D	Acthar	Corticotropin	Mallinckrodt Ph	621,884,161	77.6	NA	60	
11	D	Incruse Ellipta	Umeclidinium	Glaxosmithkline	605,138,195	13.7	2030	25	
12	D	Pradaxa[h]	Dabigatran	Boehringer Ing.	599,577,175	17.2	2027	60	
13	D	Brilinta	Ticagrelor	Astrazeneca	588,513,924	16.5	2030	60	
14	D	Xeljanz XR	Tofacitinib citrate	Pfizer	575,315,148	11.9	2034	25	
15	D	Invokana	Canagliflozin	Janssen Pharm.	571,448,119	14.8	2031	25	
Total 2028 drugs					**17,231,305,951**				
Total 2026-2028 drugs					**67,365,015,046**				**29.5 billion**

[a]*Estimates represent gross Part D spending in 2020 for Part D drugs and gross Part B spending in 2020 for Part B drugs. Spending estimates were obtained from the Medicare spending dashboards.*

[b]*Calculated as the time between drug approval and January 1 of the year that the drug is first expected to be subject to negotiation.*

[c]*Expected loss of exclusivity was estimated as the latest reported drug substance or drug product patent expiry date, superseded by any publicly announced patent settlement date.*[17-19]

[d]*Beginning in 2030, drugs from 12 to 15 years of age will be subject to a minimum 35% discount.*

[e]*Annual savings include ongoing savings from negotiated prices achieved in prior years.*

[f]*Although the entry of generic sitagliptin is expected in mid-2026, this will not disqualify Januvia from negotiation in 2026, as a generic product must have been marketed for at least 9 months prior to the implementation year for the reference product to be ineligible for negotiation.*

[g]*Spiriva and Spiriva Respimat were considered different products as they have different application numbers.*

[h]*Patent protection anticipated to expire after the first quarter of 2027, so any approved generics or biosimilars would not meet the 9-month marketing requirement prior to 2028.*

BMS = Bristol Myers Squibb; CBO = Congressional Budget Office; NA = not applicable.

products projected to be eligible for negotiation for 2026-2028 accounted for $67.4 billion in gross Medicare spending in 2020, equivalent to 33.9%) of 2020 Part D spending or 28.4% of combined Part B and D drug spending.

We expect that 2028 will be the first year when a negotiated drug becomes ineligible for negotiated prices for the first time because generic competition, as Januvia and Janumet are expected to have generic competition launch in mid-2026. This launch timeline would not result in 9 months of a marketed generic prior to the start of 2027; therefore, we anticipate negotiated prices to remain in effect through the end of 2027.

In Table 2, we report high-spend products ineligible for negotiation because of statutory requirements. In all but 7 cases, drugs were disqualified because of generic or biosimilar competition. Products disqualified from negotiation

TABLE 2 Top-Spending Drugs Ineligible for Medicare Price Negotiation, 2026-2028

Brand name	Generic name	Manufacturer	Spending in 2020[a], $	Reason ineligible
Part D drugs				
Revlimid	Lenalidomide	Celgene/BMS	5,356,050,275	Generic available
Humira	Adalimumab	Abbvie US LLC	4,166,710,387	Anticipated biosimilar in 2023
Lantus	Insulin glargine	Sanofi-Aventis	3,719,082,839	Biosimilar available
Novolog	Insulin aspart	Novo Nordisk	2,972,656,706	Interchangeable biosimilar anticipated by 2026
Humalog	Insulin lispro	Eli Lilly & Co.	2,064,366,203	Interchangeable biosimilar anticipated by 2026
Levemir Flextouch	Insulin detemir	Novo Nordisk	1,991,698,847	Interchangeable biosimilar anticipated by 2026
Victoza	Liraglutide	Novo Nordisk	1,895,291,574	Generic anticipated in 2023
Pomalyst	Pomalidomide	Celgene/BMS	1,453,860,767	Generic anticipated in 2026, and based on spending, it would not qualify until 2027
Restasis	Cyclosporine	Allergan Inc.	1,451,534,384	Generic available
Latuda	Lurasidone	Sunovion Pharma	1,317,919,887	Generic anticipated in 2023
Entresto	Sacubitril/valsartan	Novartis	1,203,043,540	Generic anticipated by 2025
Advair Diskus	Fluticasone/salmeterol	Glaxosmithkline	1,160,474,903	Generic available
Stelara	Ustekinumab	Janssen Biotech	1,106,356,248	Biosimilar anticipated in 2024
Tecfidera	Dimethyl fumarate	Biogen-Idec	1,054,984,601	Generic available
Shingrix	Varicella-zoster	Glaxosmithkline	875,670,149	Ineligible based on years since approval
Janumet	Sitagliptin/metformin	Merck Sharp & D	791,886,114	Generic anticipated in 2026, and based on spending, it would not qualify until 2027
Aubagio	Teriflunomide	Sanofi-Aventis	778,201,329	Generic anticipated in 2023
Vascepa	Icosapent ethyl	Amarin Pharma	754,811,701	Generic available
Copaxone	Glatiramer acetate	Teva Neuroscien	713,588,637	Generic available
Vimpat	Lacosamide	UCB Pharma	709,365,915	Generic available
Basaglar	Insulin glargine	Eli Lilly & Co.	689,339,162	Ineligible based on years since approval
Dexilant	Dexlansoprazole	Takeda	651,674,922	Generic available
Part B drugs				
Eylea	Aflibercept	Regeneron	3,013,081,886	Biosimilar anticipated in 2024
Prolia	Denosumab	Amgen	1,626,844,123	Biosimilar anticipated in 2025
Rituxan	Rituximab	Roche	1,295,821,133	Biosimilar available
Lucentis	Ranibizumab	Genentech	1,113,026,180	Biosimilar available
Orencia	Abatacept	BMS	1,023,001,524	Biosimilar anticipated in 2026
Neulasta	Pegfilgrastim	Amgen	899,790,555	Biosimilar available
Darzalex	Daratumumab	Johnson & Johnson	837,400,702	Not eligible until 2029 because of years since approval
Avastin	Bevacizumab	Genentech	680,539,026	Biosimilar available
Remicade	Infliximab	Janssen	663,412,142	Biosimilar available
Tecentriq	Atezolizumab	Genentech	624,194,084	Not eligible until 2030 because of years since approval
Ocrevus	Ocrelizumab	Genentech	618,708,736	Not eligible until 2031 because of years since approval
Soliris	Eculizumab	Alexion	610,425,468	Biosimilar anticipated in 2025

[a]*Estimates represent gross Part D spending in 2020 for Part D drugs and gross Part B spending in 2020 for Part B drugs. Spending estimates were obtained from the Medicare spending dashboards.*[5,10]

BMS = Bristol Myers Squibb.

include insulin products, which are expected to face competition from biosimilars by 2026, and the blockbuster Humira (adalimumab), which is expected to face biosimilar competition in 2023.

Discussion

To our knowledge, our article is the first public report of the drugs anticipated to be negotiated by CMS for benefit years 2026-2028. Our estimates differ from an earlier list of negotiation-eligible drugs for 2026 that did not consider LOE after 2022, as acknowledged by the authors.[11] With the exception of 2 insulin products, which we believe will face biosimilar competition by 2026, our list is consistent with a previous report of expected drugs to be negotiated in 2026 that did account for LOE.[12] We have excluded NovoLog (insulin aspart) from the list of drugs eligible for negotiation as patents have expired and the FDA is currently reviewing a biosimilar application.[13] We have considered Levemir (insulin detemir) ineligible for negotiation because the manufacturer reports that US patents expired in June 2019,[14] thus meeting our study exclusion criteria even though no biosimilar is yet available. Additionally, although the generic formulation of Revlimid (lenalidomide) is currently subject to volume limitations until January 2026,[15] this generic is considered "marketed" under FDA criteria, thereby excluding Revlimid from negotiation eligibility.

Some Medicare patients will benefit substantially from negotiations on these drugs, as a reduction in the drug's price will result in lower coinsurance and liability during the deductible phase. Overall, negotiations are projected by the CBO to reduce premiums, resulting in lower costs for all Medicare beneficiaries.[4,16] Notably, the minimum price reductions listed almost certainly underrepresent the price reductions that will be achieved for the Part D drugs, as the negotiated price is required to be below the existing average net price of the drug, which includes confidential rebates. Thus, Medicare patients may see their cost sharing fall by amounts greater than reflected by the minimum price reductions reported, as their cost sharing will reflect, at minimum, existing net prices.

Overall, Medicare negotiation will benefit patients on the specific medications identified across some of the most common disease areas while reducing total Medicare drug spending. The Inflation Reduction Act coupled CMS negotiation with substantial reforms to the Medicare Part D benefit design, most notably a $2,000 out-of-pocket cap. Absent CMS negotiation, these benefit changes are estimated to increase Medicare spending by $30 billion, but the savings generated through CMS negotiation offset these increases.[4]

LIMITATIONS

Our findings are subject to 2 main limitations. First, our selection of top-spending drugs is based on data from 2020, the most recent available at the time of analysis. Changes in drug utilization and pricing over time may affect which drugs are ultimately selected for negotiation based on total spending in the year prior to negotiation. Second, our list of drugs eligible for negotiation is subject to the uncertain outcomes of ongoing patent litigation, which could affect the date of predicted generic or biosimilar entry.

Conclusions

We estimate that Medicare will negotiate 38 Part D and 2 Part B drugs in 2026-2028, including 7 inhalers, 8 antidiabetics, 5 kinase inhibitors, and 3 oral anticoagulants. Combined, the 40 products eligible for negotiation in 2026-2028 accounted for $67.4 billion in gross Medicare spending in 2020. By identifying a list of drugs likely to be negotiated by CMS, we hope to provide researchers, policymakers, prescribers, and patient advocates with expectations on which drugs will see reductions in beneficiary cost sharing.

DISCLOSURES

This work was funded by the West Health Policy Center. Dr Hernandez reports consulting fees from Pfizer and Bristol Myers Squibb, outside of the submitted work.

REFERENCES

1. Inflation Reduction Act of 2022. HR 5376, 117th Cong (2022). Accessed January 19, 2023. https://www.congress.gov/bill/117th-congress/house-bill/5376/text

2. Center for Drug Evaluation and Research. Marketing status notifications under section 506I of the Federal Food, Drug, and Cosmetic Act. US Food and Drug Administration. Accessed January 24, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-status-notifications-under-section-506i-federal-food-drug-and-cosmetic-act

3. Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program: Next steps in implementation for initial price applicability year 2026. Published January 11, 2023. Accessed January 19, 2023. https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf

4. Congressional Budget Office. Estimated budgetary effects of Public Law 117-169, to provide for reconciliation pursuant to Title II of S. Con. Res. 14. Published 2022. Accessed September 29, 2022. https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf

5. Medicare Part D spending dashboard. Centers for Medicare & Medicaid Services. Accessed September 29, 2022. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug

6. Medicare Part B spending dashboard. Centers for Medicare & Medicaid Services. Accessed January 19, 2023. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug

7. Drugs@FDA database. US Food and Drug Administration. Accessed January 19, 2023. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

8. Center for Drug Evaluation and Research. Approved drug products with therapeutic equivalence evaluations|Orange Book. US Food and Drug Administration. Accessed September 14, 2022. https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book

9. Cardinal Health. 2022 Biosimilars Report: The US journey and path ahead. Accessed September 9, 2022. https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-2022-biosimilars-report.pdf

10. Medicaid spending dashboard. Centers for Medicare & Medicaid Services. Accessed January 19, 2023. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicaid-spending-by-drug

11. Hwang TJ, Kesselheim AS, Rome BN. New reforms to prescription drug pricing in the US: Opportunities and challenges. JAMA. 2022;328(11):1041-2. doi:10.1001/jama.2022.15268

12. Johnson M, Nayak R, Kishore S. Which drug prices will Medicare negotiate first? A physicians' perspective. *Health Affairs Forefront*. September 30, 2022. doi:10.1377/forefront.20220929.242021

13. Hagen T. Investigators report high similarity between NovoLog and biosimilar candidate. Managed Healthcare Executive. Published October 20, 2022. Accessed January 24, 2023. https://www.managedhealthcareexecutive.com/view/investigators-report-high-similarity-between-novolog-and-biosimilar-candidate

14. Novo Nordisk. Annual Report to the US Securities and Exchange Commission: Form 20-F. Accessed January 19, 2023. https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2020/Novo-Nordisk-Form-20-f-2019.pdf

15. Celgene settles US REVLIMID® patent litigation with Alvogen. Celegene. Accessed January 24, 2023. https://ir.celgene.com/press-releases-archive/press-release-details/2019/Celgene-Settles-US-REVLIMID-Patent-Litigation-with-Alvogen/default.aspx

16. CBO estimates drug savings for reconciliation. Committee for a responsible federal budget. Accessed January 25, 2023. https://www.crfb.org/blogs/cbo-estimates-drug-savings-reconciliation

17. US Securities and Exchange Commission. Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31,2021. Form 10-K. Bristol-Myers Squibb Company. Accessed September 29, 2022. https://d18rn0p25nwr6d.cloudfront.net/CIK-0000014272/f4a6942f-7e0d-4d3e-9ef4-b3b0a9d617d7.pdf

18. US District Court rules in favor of Merck in sitagliptin phosphate patent lawsuit. Merck. Published September 22, 2022. Accessed September 29, 2022. https://www.merck.com/news/u-s-district-court-rules-in-favor-of-merck-in-sitagliptin-phosphate-patent-lawsuit/

19. De Backer M, Rommel C, Olerich S. Transforming pharma to deliver sustainable longterm growth. Bayer Capital Markets Day. Published March 10, 2021. Accessed September 29, 2022. https://www.bayer.com/sites/default/files/BayerCMD2021_Pharma_Presentation_0.pdf

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2024, the foregoing was electronically filed with the Clerk of Court using the appellate CM/ECF system.

Dated: July 12, 2024

/*s*/ Jacob (Yaakov) M. Roth
Jacob (Yaakov) M. Roth

Counsel for Appellant Bristol Myers Squibb Co.

Nos. 24-1820 & 24-1821

United States Court of Appeals for the Third Circuit

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey, Nos. 3:23-cv-03335 & 3:23-cv-03818

JOINT APPENDIX VOLUME 3
(JA411-JA799)

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, NY 10281

Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102

Counsel for Plaintiff-Appellant Bristol Myers Squibb Company

Noel J. Francisco
Yaakov M. Roth
Brett A. Shumate
Charles E.T. Roberts
John Henry Thompson
Louis J. Capozzi III
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
(202) 879-3939

Robert A. Long, Jr.
Kevin F. King
Michael M. Maya
Bradley K. Ervin
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

Counsel for Plaintiff-Appellant Janssen Pharmaceuticals, Inc.

[additional counsel listed on inside cover]

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
MICHAEL S. RAAB
LINDSEY POWELL
STEVEN A. MYERS
DAVID L. PETERS
CATHERINE PADHI
Attorneys, Appellate Staff
Civil Division, Room 7712
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 514-5091

Counsel for Defendants-Appellees

TABLE OF CONTENTS

Date Filed	Document	ECF No.	Page
Volume 1 of 3			
4/29/2024	Opinion, *Bristol Myers Squibb Co. v. Becerra*, No. 3: 23-cv-03335, and *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JBD (D.N.J. Apr. 29, 2024)	110 (*BMS*) 98 (*Janssen*)	JA1
4/29/2024	Order Denying Motion for Summary Judgment and Granting Cross-Motion for Summary Judgment, *Bristol Myers Squibb Co. v. Becerra*, No. 3: 23-cv-03335, and *Janssen v. Becerra*, No. 3:23-cv-03818-ZNQ-JBD (D.N.J. Apr. 29, 2024)	111 (*BMS*) 99 (*Janssen*)	JA27
4/29/2024	Notice of Appeal (Bristol Myers Squibb Company)	113 (*BMS*)	JA29
4/30/2024	Notice of Appeal (Janssen Pharmaceuticals, Inc.)	100 (*Janssen*)	JA31
Volume 2 of 3			
	Docket Sheet, *Bristol Myers Squibb Company v. Becerra*		JA33
6/16/2023	Complaint, *Bristol Myers Squibb Company v. Becerra*	1 (*BMS*)	JA52
8/16/2023	Declaration of Christopher T. Mancill in Support of Plaintiff's Motion for Summary Judgment	36-1	JA82
8/16/2023	Declaration of Toni-Ann Citera in Support of Plaintiff's Motion for Summary Judgment	36-2	JA96
8/16/2023	Citera Decl. Ex. A: *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, CMS (June 30, 2023)	36-2	JA99

Date Filed	Document	ECF No.	Page
8/16/2023	Citera Decl. Ex. B: Medicare Drug Price Negotiation Program Agreement	36-2	JA298
8/16/2023	Citera Decl. Ex. C: *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*, CMS (Mar. 15, 2023)	36-2	JA311
8/16/2023	Citera Decl. Ex. D: S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation*, 2026-2028, 29 JMCP 229 (Mar. 2023)	36-2	JA403
Volume 3 of 3			
	Docket Sheet, *Janssen v. Becerra*		JA411
7/18/2023	Complaint, *Janssen v. Becerra*	1 (*Janssen*)	JA429
8/16/2023	Declaration of Jeff Chiesa in Support of Plaintiff's Motion for Summary Judgment	30-2	JA474
8/16/2023	Chiesa Decl. Ex. A: CMS Document, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2025"	30-3	JA477
8/16/2023	Chiesa Decl. Ex. B: Medicare Drug Price Negotiation Program Agreement	30-4	JA676
8/16/2023	Chiesa Decl. Ex. C: Study by Sean Dickson and Dr. Inmaculada Hernandez, "Drugs Likely Subject to Medicare Negotiation 2026–2028"	30-5	JA689
8/16/2023	Chiesa Decl. Ex. D: Congressional Research Service report, "Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)"	30-6	JA697

Date Filed	Document	ECF No.	Page
8/16/2023	Chiesa Decl. Ex. E: Joint Committee on Taxation November 2021 publication, "Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The 'Build Back Better Act,' As Passed By The House of Representatives: Fiscal Years 2022–2031"	30-7	JA735
8/16/2023	Chiesa Decl. Ex. F: Congressional Budget Office 2022 publication, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act"	30-8	JA746
8/16/2023	Chiesa Decl. Ex. G: Testimony of CMS Administrator Brooks-LaSure before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health	30-9	JA786
8/16/2023	Declaration of Blasine Penkowski in Support of Janssen's Motion for Summary Judgment	30-10	JA791

APPEAL,CLOSED

U.S. District Court
District of New Jersey [LIVE] (Trenton)
CIVIL DOCKET FOR CASE #: 3:23-cv-03818-ZNQ-JBD

JANSSEN PHARMACEUTICALS, INC. v. BECERRA et al
Assigned to: Judge Zahid N. Quraishi
Referred to: Magistrate Judge J. Brendan Day
Related Cases: 3:23-cv-14221-ZNQ-JBD
3:23-cv-20814-ZNQ-JBD
Case in other court: Third Circuit, 24-01821
Cause: 28:2201 Declaratory Judgment

Date Filed: 07/18/2023
Date Terminated: 04/29/2024
Jury Demand: None
Nature of Suit: 440 Civil Rights: Other
Jurisdiction: U.S. Government Defendant

Plaintiff

JANSSEN PHARMACEUTICALS, INC. represented by **JEFFREY SCOTT CHIESA**
CHIESA SHAHINIAN & GIANTOMASI PC
105 EISENHOWER PARKWAY
ROSELAND, NJ 07068
973-530-2050
Email: jchiesa@csglaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

RONALD LAWRENCE ISRAEL
CHIESA SHAHINIAN & GIANTOMASI PC
105 EISENHOWER PARKWAY
ROSELAND, NJ 07068
973-530-2045
Fax: 973-530-2245
Email: risrael@csglaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

DAVID A. LUTTINGER
COVINGTON & BURLING LLP
THE NEW YORK TIMES BUILDING
620 EIGHTH AVENUE
NEW YORK, NY 10018
212-841-1000
Email: dluttinger@cov.com
ATTORNEY TO BE NOTICED

V.

Defendant

XAVIER BECERRA
in his official capacity as Secretary of Health and Human Services

represented by **ALEXANDER V SVERDLOV**
DOJ-CIV
POC AGOSTINHO, JEAN
1100 L ST., N.W.
WASHINGTON, DC 20530
202-305-8550
Email: alexander.v.sverdlov@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

BRIAN DAVID NETTER
DOJ-CIV
CIVIL DIVISION
950 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20530
202-514-2000
Email: brian.netter@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
U.S. DEPARTMENT OF JUSTICE
CIVIL DIVISION, FEDERAL PROGRAMS BRANCH
1100 L STREET NW
WASHINGTON, DC 20005
202-305-8576
Email: stephen.pezzi@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
DOJ-CIV
DEPARTMENT OF JUSTICE
1100 L STREET NW
WASHINGTON, DC 20005
202-451-7729
Email: cassandra.m.snyder@usdoj.gov
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
DOJ-CIV
FEDERAL PROGRAMS BRANCH, CIVIL DIVISION
1100 L ST. NW
WASHINGTON, DC 20005
202-880-0282
Email: christine.l.coogle@usdoj.gov
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
DOJ-USAO
DISTRICT OF NEW JERSEY
401 MARKET STREET

P.O. BOX 2098
CAMDEN, NJ 08101
856-757-5031
Fax: 856-757-5416
Email: heather.costanzo@usdoj.gov
ATTORNEY TO BE NOTICED

Defendant

DEPARTMENT OF HEALTH AND HUMAN SERVICES

represented by **ALEXANDER V SVERDLOV**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

BRIAN DAVID NETTER
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
(See above for address)
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
(See above for address)
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

CHIQUITA BROOKS-LASURE
in her official capacity as Administrator of Centers for Medicare & Medicaid Services

represented by **ALEXANDER V SVERDLOV**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

BRIAN DAVID NETTER
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
(See above for address)
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
(See above for address)
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

CENTERS FOR MEDICARE AND MEDICAID SERVICES

represented by **ALEXANDER V SVERDLOV**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

BRIAN DAVID NETTER
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

STEPHEN MICHAEL PEZZI
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

CASSANDRA SNYDER
(See above for address)
ATTORNEY TO BE NOTICED

CHRISTINE L. COOGLE
(See above for address)
ATTORNEY TO BE NOTICED

HEATHER CARNEY COSTANZO
(See above for address)
ATTORNEY TO BE NOTICED

Amicus

FRESENIUS KABI USA, LLC

represented by **JUSTIN TAYLOR QUINN**
ROBINSON MILLER LLC
IRONSIDE NEWARK
110 Edison Place, Suite 302
NEWARK, NJ 07102
973-690-5400
Email: jquinn@rwmlegal.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Public Citizen

represented by **ANDREW M. MILZ**
FLITTER MILZ, P.C.
1814 EAST ROUTE 70
SUITE 350
CHERRY HILL, NJ 08003

856-396-0600
Fax: 833-775-3450
Email: amilz@consumerslaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Patients for Affordable Drugs Now represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Doctors for America represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Protect Our Care represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Families USA represented by **ANDREW M. MILZ**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

AARP, AARP Foundation
601 E Street
Washington, DC 20049

represented by **GLEN D. SAVITS**
GREEN SAVITS, LLC
25B VREELAND ROAD
SUITE 207
FLORHAM PARK, NJ 07932
(973) 695-7777
Fax: (973) 695-7788
Email: gsavits@greensavits.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Intellectual Property Law and Health Law Scholars represented by **JAMES E. CECCHI**
CARELLA BYRNE CECCHI BRODY & AGNELLO, P.C.
5 BECKER FARM ROAD
ROSELAND, NJ 07068
(973) 994-1700
Fax: (973) 994-1744
Email: jcecchi@carellabyrne.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

American Public Health Association

represented by **MADELINE GITOMER**
Democracy Forward
P.O. Box 34553
Washington, DC 20043
202-448-9090
Email: mgitomer@democracyforward.org
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

American College of Physicians

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Society of General Internal Medicine

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

American Geriatrics Society

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

American Society of Hematology

represented by **MADELINE GITOMER**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Nationally Recognized Healthcare and Medicare Experts

represented by **JOHN W. LEARDI**
BUTTACI LEARDI & WERNER LLC
212 CARNEGIE CENTER
SUITE 202
PRINCETON, NJ 08540
609-799-5150
Fax: 609-799-5180
Email: jwleardi@buttacilaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

LAW SCHOLARS

represented by **DONALD A. ECKLUND**
CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.
5 BECKER FARM ROAD
ROSELAND, NJ 07068
(973) 994-1700

Fax: (973) 994-1744
Email: decklund@carellabyrne.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Economists and Scholars of Health Policy as Amici Curiae

represented by

JAMES C. SHAH
MILLER SHAH LLP
2 HUDSON PLACE
SUITE 100
HOBOKEN, NJ 07030
856-526-1100
Fax: 866-300-7367
Email: jcshah@millershah.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ALEC BERIN
Miller Shah LLP
1845 Walnut Street
Suite 806
Philadelphia, PA 19103
610-891-9880
Fax: 866-300-7367
Email: ajberin@millershah.com
ATTORNEY TO BE NOTICED

Amicus

Abrams Institute for Freedom of Expression

represented by

FLAVIO L. KOMUVES
WEISSMAN & MINTZ LLC
220 DAVIDSON AVENUE
SUITE 410
SOMERSET, NJ 08873
732-563-4565
Email: fkomuves@weissmanmintz.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Constitutional Accountability Center

represented by

DANIEL R. LEATHERS
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 HUDSON STREET
8TH FLOOR
NEW YORK, NY 10013
212-355-9500
Fax: 212-355-9592
Email: dleathers@lchb.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Amicus

Alliance for Aging Research represented by **STEPHEN M. BALDINI**
AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.
ONE BRYANT PARK
NEW YORK, NY 10036
212-872-1000
Email: sbaldini@akingump.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
07/18/2023	1	COMPLAINT against XAVIER BECERRA, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Filing and Admin fee $ 402 receipt number ANJDC-14462307), filed by JANSSEN PHARMACEUTICALS, INC.. (Attachments: # 1 Civil Cover Sheet, # 2 Certification Pursuant to Local Civil Rule 11.2)(LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023	2	Corporate Disclosure Statement by JANSSEN PHARMACEUTICALS, INC. identifying DePuy Synthes, Inc. as Corporate Parent.. (LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023	3	Request for Summons to be Issued by JANSSEN PHARMACEUTICALS, INC. as to XAVIER BECERRA. (LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023	4	Request for Summons to be Issued by JANSSEN PHARMACEUTICALS, INC. as to DEPARTMENT OF HEALTH AND HUMAN SERVICES. (LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023	5	Request for Summons to be Issued by JANSSEN PHARMACEUTICALS, INC. as to CHIQUITA BROOKS-LASURE. (LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023	6	Request for Summons to be Issued by JANSSEN PHARMACEUTICALS, INC. as to CENTERS FOR MEDICARE AND MEDICAID SERVICES. (LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023	7	Request for Summons to be Issued by JANSSEN PHARMACEUTICALS, INC. as to XAVIER BECERRA, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES. (LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023	8	Request for Summons to be Issued by JANSSEN PHARMACEUTICALS, INC. as to XAVIER BECERRA, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES. (LUTTINGER, DAVID) (Entered: 07/18/2023)
07/18/2023		Judge Zahid N. Quraishi and Magistrate Judge Rukhsanah L. Singh added. (jdg) (Entered: 07/18/2023)
07/18/2023	9	SUMMONS ISSUED as to XAVIER BECERRA, CHIQUITA BROOKS-LASURE, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES. Attached is the official court Summons, please fill out Defendant and Plaintiffs attorney information and serve. (jdg) (Entered: 07/18/2023)
07/21/2023		Magistrate Judge J. Brendan Day added. Magistrate Judge Rukhsanah L. Singh no longer assigned to case. (jjc,) (Entered: 07/21/2023)

07/21/2023	10	NOTICE of Appearance by STEPHEN MICHAEL PEZZI on behalf of All Defendants (PEZZI, STEPHEN) (Entered: 07/21/2023)
07/21/2023	11	NOTICE by All Defendants *of Designation of Agent for Service Under Local Civil Rule 101.1(f)* (PEZZI, STEPHEN) (Entered: 07/21/2023)
07/21/2023	12	NOTICE of Appearance by CHRISTINE L. COOGLE on behalf of All Defendants (COOGLE, CHRISTINE) (Entered: 07/21/2023)
07/28/2023	13	Letter from Defendants regarding the parties' joint proposed schedule. (Attachments: # 1 Text of Proposed Order)(PEZZI, STEPHEN) (Entered: 07/28/2023)
07/31/2023	14	ORDER that the herein schedule shall govern further proceedings in this case. It is ORDERED that the parties need not file statements of material fact under Local Civil Rule 56.1(a) and it is further ORDERED that Defendants need not file an answer to the Complaints. Signed by Judge Zahid N. Quraishi on 7/31/2023. (mlh) (Entered: 07/31/2023)
08/01/2023	15	NOTICE of Appearance by JEFFREY SCOTT CHIESA on behalf of JANSSEN PHARMACEUTICALS, INC. (CHIESA, JEFFREY) (Entered: 08/01/2023)
08/01/2023	16	NOTICE of Appearance by RONALD LAWRENCE ISRAEL on behalf of JANSSEN PHARMACEUTICALS, INC. (ISRAEL, RONALD) (Entered: 08/01/2023)
08/04/2023	17	SUMMONS Returned Executed by JANSSEN PHARMACEUTICALS, INC.. All Defendants. (ISRAEL, RONALD) (Entered: 08/04/2023)
08/14/2023	18	MOTION for Leave to Appear Pro Hac Vice *of Kevin F. King* by JANSSEN PHARMACEUTICALS, INC.. (Attachments: # 1 Certification of Jeffrey S. Chiesa, Esq., # 2 Certification of Kevin F. King, Esq., # 3 Text of Proposed Order, # 4 Certificate of Service)(CHIESA, JEFFREY) (Entered: 08/14/2023)
08/14/2023	19	MOTION for Leave to Appear Pro Hac Vice *of Robert A. Long, Jr.* by JANSSEN PHARMACEUTICALS, INC.. (Attachments: # 1 Certification of Jeffrey S. Chiesa, Esq., # 2 Certification of Robert A. Long, Jr., # 3 Text of Proposed Order, # 4 Certificate of Service)(CHIESA, JEFFREY) (Entered: 08/14/2023)
08/14/2023	20	MOTION for Leave to Appear Pro Hac Vice *of Bradley K. Ervin* by JANSSEN PHARMACEUTICALS, INC.. (Attachments: # 1 Certification of Jeffrey S. Chiesa, Esq., # 2 Certification of Bradley K. Ervin, # 3 Text of Proposed Order, # 4 Certificate of Service)(CHIESA, JEFFREY) (Entered: 08/14/2023)
08/14/2023	21	MOTION for Leave to Appear Pro Hac Vice *of MaKade C. Claypool* by JANSSEN PHARMACEUTICALS, INC.. (Attachments: # 1 Certification of Jeffrey S. Chiesa, Esq., # 2 Certification of Makade C. Claypool, # 3 Text of Proposed Order, # 4 Certificate of Service)(CHIESA, JEFFREY) (Entered: 08/14/2023)
08/15/2023		Set Deadlines as to 21 MOTION for Leave to Appear Pro Hac Vice *of MaKade C. Claypool*, 19 MOTION for Leave to Appear Pro Hac Vice *of Robert A. Long, Jr.*, 20 MOTION for Leave to Appear Pro Hac Vice *of Bradley K. Ervin*, 18 MOTION for Leave to Appear Pro Hac Vice *of Kevin F. King*. Motion set for 9/18/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg,) (Entered: 08/15/2023)
08/16/2023	22	ORDER granting 18 Motion for Leave to Appear Pro Hac Vice as to Kevin King. Signed by Magistrate Judge J. Brendan Day on 8/15/2023. (mg,) (Entered: 08/16/2023)

08/16/2023	23	ORDER granting 19 Motion for Leave to Appear Pro Hac Vice as to Robert A. Long, Jr. Signed by Magistrate Judge J. Brendan Day on 8/15/2023. (mg,) (Entered: 08/16/2023)
08/16/2023	24	ORDER granting 20 Motion for Leave to Appear Pro Hac Vice as to Bradley K. Ervin. Signed by Magistrate Judge J. Brendan Day on 8/15/2023. (mg,) (Entered: 08/16/2023)
08/16/2023	25	ORDER granting 21 Motion for Leave to Appear Pro Hac Vice as to MaKade C. Claypool. Signed by Magistrate Judge J. Brendan Day on 8/15/22023. (mg) (Entered: 08/16/2023)
08/16/2023	26	Notice of Request by Pro Hac Vice Makade C. Claypool, Esq. to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14534564.) (CHIESA, JEFFREY) (Entered: 08/16/2023)
08/16/2023	27	Notice of Request by Pro Hac Vice Bradley K. Ervin, Esq. to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14534710.) (CHIESA, JEFFREY) (Entered: 08/16/2023)
08/16/2023	28	Notice of Request by Pro Hac Vice Kevin F. King, Esq. to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14534803.) (CHIESA, JEFFREY) (Entered: 08/16/2023)
08/16/2023	29	Notice of Request by Pro Hac Vice Robert A. Long, Jr., Esq. to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14534902.) (CHIESA, JEFFREY) (Entered: 08/16/2023)
08/16/2023	30	MOTION for Summary Judgment by JANSSEN PHARMACEUTICALS, INC.. (Attachments: # 1 Brief, # 2 Declaration of Jeff Chiesa, # 3 Exhibit A to Chiesa Declaration, # 4 Exhibit B to Chiesa Declaration, # 5 Exhibit C to Chiesa Declaration, # 6 Exhibit D to Chiesa Declaration, # 7 Exhibit E to Chiesa Declaration, # 8 Exhibit F to Chiesa Declaration, # 9 Exhibit G to Chiesa Declaration, # 10 Declaration of Blasine Penkowski, # 11 Text of Proposed Order, # 12 Certificate of Service)(CHIESA, JEFFREY) (Entered: 08/16/2023)
08/17/2023		Pro Hac Vice counsel, MAKADE C. CLAYPOOL, BRADLEY K. ERVIN, KEVIN F. KING and ROBERT A. LONG, JR., has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (jdg) (Entered: 08/17/2023)
08/17/2023		Set Deadlines as to 30 MOTION for Summary Judgment . Motion set for 9/18/2023 before Judge Zahid N. Quraishi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg) (Entered: 08/17/2023)
08/29/2023	31	MOTION for Leave to Appear Amicus Curiae by FRESENIUS KABI USA, LLC. (Attachments: # 1 Brief)(QUINN, JUSTIN) (Entered: 08/29/2023)
08/30/2023		Set Deadlines as to 31 MOTION for Leave to Appear Amicus Curiae . Motion set for 10/2/2023 before Judge Zahid N. Quraishi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg) (Entered: 08/30/2023)
10/16/2023	32	NOTICE of Appearance by ALEXANDER V SVERDLOV on behalf of All Defendants (SVERDLOV, ALEXANDER) (Entered: 10/16/2023)

10/16/2023	33	Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion* by All Defendants. Responses due by 11/10/2023. (Attachments: # 1 Brief, # 2 Text of Proposed Order)(SVERDLOV, ALEXANDER) (Entered: 10/16/2023)
10/17/2023		Set Deadlines as to 33 Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion*. Motion set for 11/20/2023 before Judge Zahid N. Quraishi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg) (Entered: 10/17/2023)
10/17/2023	34	MOTION for Leave to Appear Amicus Curiae by Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA. (Attachments: # 1 Brief)(MILZ, ANDREW) (Entered: 10/17/2023)
10/17/2023	35	Corporate Disclosure Statement by Doctors for America, Families USA, Patients for Affordable Drugs Now, Protect Our Care, Public Citizen. (MILZ, ANDREW) (Entered: 10/17/2023)
10/18/2023	36	Exhibit to 34 Appear Amicus Curiae by Doctors for America, Families USA, Patients for Affordable Drugs Now, Protect Our Care, Public Citizen. (MILZ, ANDREW) (Entered: 10/18/2023)
10/18/2023	37	Amicus Curiae APPEARANCE entered by GLEN D. SAVITS on behalf of AARP, AARP Foundation. (SAVITS, GLEN) (Entered: 10/18/2023)
10/19/2023	38	MOTION for Leave to Appear Pro Hac Vice *Granting the Pro Hac Vice Admission of Meryl D. Grenadier* by AARP, AARP Foundation. (Attachments: # 1 Declaration of Glen D. Savits, # 2 Declaration of Meryl D. Grenadier, # 3 Text of Proposed Order, # 4 Certificate of Service)(SAVITS, GLEN) (Entered: 10/19/2023)
10/19/2023	39	MOTION for Leave to Appear Pro Hac Vice by Intellectual Property Law and Health Law Scholars. (Attachments: # 1 Declaration of James E. Cecchi, # 2 Declaration of Hannah W. Brennan, # 3 Declaration of Claudia Morera, # 4 Declaration of Rebekah GlickmanSimon, # 5 Text of Proposed Order)(CECCHI, JAMES) (Entered: 10/19/2023)
10/20/2023		Set Deadlines as to 39 MOTION for Leave to Appear Pro Hac Vice . Motion set for 11/20/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg) (Entered: 10/20/2023)
10/20/2023		Set Deadlines as to 38 MOTION for Leave to Appear Pro Hac Vice *Granting the Pro Hac Vice Admission of Meryl D. Grenadier*. Motion set for 11/20/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jal,) (Entered: 10/20/2023)
10/20/2023	40	ORDER granting 39 Motion for Leave to Appear Pro Hac Vice as to, Hannah Brennan, Claudia Morera, and Rebekah Glickman-Simon. Signed by Magistrate Judge J. Brendan Day on 10/20/2023. (jdg) (Entered: 10/20/2023)
10/20/2023	41	ORDER granting 38 Motion for Leave to Appear Pro Hac Vice as to, Meryl D. Grenadier. Signed by Magistrate Judge J. Brendan Day on 10/20/2023. (jdg) (Entered: 10/20/2023)
10/23/2023	42	MOTION for Leave to Appear Amicus Curiae by AARP, AARP Foundation. (Attachments: # 1 Brief, # 2 Text of Proposed Order)(SAVITS, GLEN) (Entered:

		10/23/2023)
10/23/2023	43	Consent MOTION for Leave to Appear Amicus Curiae by American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology. (Attachments: # 1 Brief Proposed Amicus, # 2 Proposed Order)(GITOMER, MADELINE) (Entered: 10/23/2023)
10/23/2023	44	Corporate Disclosure Statement by American College of Physicians, American Geriatrics Society, American Public Health Association, American Society of Hematology, Society of General Internal Medicine. (GITOMER, MADELINE) (Entered: 10/23/2023)
10/23/2023	45	Consent MOTION for Leave to Appear Pro Hac Vice by American College of Physicians, American Geriatrics Society, American Public Health Association, American Society of Hematology, Society of General Internal Medicine. (Attachments: # 1 Declaration Sponsoring Attorney, # 2 Declaration Burra, # 3 Declaration Seel, # 4 Declaration Thurston, # 5 Proposed Order)(GITOMER, MADELINE) (Entered: 10/23/2023)
10/23/2023	46	MOTION for Leave to Appear Amicus Curiae by Nationally Recognized Healthcare and Medicare Experts. (Attachments: # 1 Brief in Support of Motion to File a Brief as Amici Curiae in Support of Defendants' Cross Motion for Summary Judgment and in Opposition to Plaintiffs' Motions for Summary Judgment, # 2 Text of Proposed Order)(LEARDI, JOHN) (Entered: 10/23/2023)
10/23/2023	47	Consent MOTION for Leave to Appear Pro Hac Vice by Nationally Recognized Healthcare and Medicare Experts. (Attachments: # 1 Certification of John W. Leardi, # 2 Certification of William B. Schultz, # 3 Certification of Margaret M. Dotzel, # 4 Certification of Alyssa M. Howard, # 5 Text of Proposed Order, # 6 Certificate of Service)(LEARDI, JOHN) (Entered: 10/23/2023)
10/23/2023	48	MOTION for Leave to Appear Amicus Curiae by LAW SCHOLARS. (Attachments: # 1 Brief, # 2 Text of Proposed Order, # 3 Proposed Brief of Amici Curiae Law Scholars) (ECKLUND, DONALD) (Entered: 10/23/2023)
10/23/2023	49	NOTICE of Appearance by ALEC BERIN on behalf of Economists and Scholars of Health Policy as Amici Curiae (BERIN, ALEC) (Entered: 10/23/2023)
10/23/2023	50	NOTICE of Appearance by JAMES C. SHAH on behalf of Economists and Scholars of Health Policy as Amici Curiae (SHAH, JAMES) (Entered: 10/23/2023)
10/23/2023	51	MOTION for Leave to File by Economists and Scholars of Health Policy as Amici Curiae. (Attachments: # 1 Brief of Economists and Scholars of Health Policy as Amici Curiae in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment)(SHAH, JAMES) (Entered: 10/23/2023)
10/24/2023		Set Deadlines as to 42 MOTION for Leave to Appear Amicus Curiae , 51 MOTION for Leave to File , 47 Consent MOTION for Leave to Appear Pro Hac Vice , 48 MOTION for Leave to Appear Amicus Curiae , 45 Consent MOTION for Leave to Appear Pro Hac Vice , 46 MOTION for Leave to Appear Amicus Curiae , 43 Consent MOTION for Leave to Appear Amicus Curiae . Motion set for 11/6/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (kht) (Entered: 10/24/2023)
10/27/2023	52	ORDER granting 45 Motion for Leave to Appear Pro Hac Vice as to ANANDA V. BURRA, BENJAMIN SEEL and ROBIN F. THURSTON. Signed by Magistrate Judge J. Brendan Day on 10/27/2023. (jdg) (Entered: 10/27/2023)

10/27/2023	53	ORDER granting 47 Motion for Leave to Appear Pro Hac Vice as to, WILLIAM B. SCHULTZ, MARGARET M. DOTZEL, and ALYSSA M. HOWARD. Signed by Magistrate Judge J. Brendan Day on 10/27/2023. (jdg) (Entered: 10/27/2023)
10/30/2023	54	MOTION for Leave to Appear Pro Hac Vice *of Wendy Liu* by Doctors for America, Families USA, Patients for Affordable Drugs Now, Protect Our Care, Public Citizen. (Attachments: # 1 Certification of Andrew M. Milz, # 2 Text of Proposed Order)(MILZ, ANDREW) (Entered: 10/30/2023)
10/30/2023	55	MOTION for Leave to Appear Amicus Curiae by Abrams Institute for Freedom of Expression. (Attachments: # 1 Text of Proposed Order, # 2 Brief in support of motion for leave to file amicus brief, # 3 Brief Exhibit A (MERITS AMICUS BRIEF))(KOMUVES, FLAVIO) (Entered: 10/30/2023)
10/31/2023		Set Deadlines as to 54 MOTION for Leave to Appear Pro Hac Vice *of Wendy Liu*. Motion set for 12/4/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (amv) (Entered: 10/31/2023)
10/31/2023	56	Notice of Request by Pro Hac Vice Benjamin Seel to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14835369.) (GITOMER, MADELINE) (Entered: 10/31/2023)
10/31/2023	57	Notice of Request by Pro Hac Vice Ananda V. Burra to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14835397.) (GITOMER, MADELINE) (Entered: 10/31/2023)
10/31/2023	58	Notice of Request by Pro Hac Vice Robin F. Thurston to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14835429.) (GITOMER, MADELINE) (Entered: 10/31/2023)
11/01/2023		Pro Hac Vice counsel, BENJAMIN SEEL, ANANDA V. BURRA and ROBIN F. THURSTON, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (kht) (Entered: 11/01/2023)
11/01/2023	59	MOTION for Leave to Appear Pro Hac Vice *of David A. Schulz* by Abrams Institute for Freedom of Expression. (Attachments: # 1 Declaration of David A. Schulz, # 2 Declaration of Flavio L. Komuves, # 3 Text of Proposed Order Proposed Order) (KOMUVES, FLAVIO) (Entered: 11/01/2023)
11/01/2023	60	MOTION for Leave to File *Amicus Curiae Brief in Support of Defendants* by Constitutional Accountability Center. (Attachments: # 1 Proposed Brief of Amicus Curiae, # 2 Corporate Disclosure Statement, # 3 Proposed Order)(LEATHERS, DANIEL) (Entered: 11/01/2023)
11/01/2023	61	MOTION for Leave to Appear Pro Hac Vice *as to Elizabeth Wydra, Brianne Gorod, and Nina Henry* by Constitutional Accountability Center. (Attachments: # 1 Certification of Daniel R. Leathers, # 2 Certification of Elizabeth Wydra, # 3 Certification of Brianne Gorod, # 4 Certification of Nina Henry, # 5 Proposed Order)(LEATHERS, DANIEL) (Entered: 11/01/2023)
11/01/2023	62	Notice of Request by Pro Hac Vice Meryl D. Grenadier to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14839629.) (SAVITS, GLEN) (Entered: 11/01/2023)

11/02/2023	63	Letter from Defendants on behalf of all parties requesting a 14-day extension of all remaining briefing deadlines. (Attachments: # 1 Text of Proposed Order)(PEZZI, STEPHEN) (Entered: 11/02/2023)
11/02/2023		Set Deadlines as to 61 MOTION for Leave to Appear Pro Hac Vice *as to Elizabeth Wydra, Brianne Gorod, and Nina Henry*, 60 MOTION for Leave to File *Amicus Curiae Brief in Support of Defendants*, 59 MOTION for Leave to Appear Pro Hac Vice *of David A. Schulz*. Motion set for 12/4/2023 before Magistrate Judge J. Brendan Day. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (kht) (Entered: 11/02/2023)
11/02/2023		Pro Hac Vice counsel, MERYL D. GRENADIER, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (jal,) (Entered: 11/02/2023)
11/03/2023	64	CONSENT ORDER that Plaintiffs' combined replies in support of their motions for summary judgment and oppositions to Defendants' cross-motion for summary judgment shall be due 11/24/2023 and Defendants' reply in support of their cross-motion for summary judgment shall be due 12/22/2023. Signed by Judge Zahid N. Quraishi on 11/3/2023. (mlh) (Entered: 11/03/2023)
11/03/2023	65	Notice of Request by Pro Hac Vice William B. Schultz to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14846566.) (LEARDI, JOHN) (Entered: 11/03/2023)
11/03/2023	66	Notice of Request by Pro Hac Vice Margaret M. Dotzel to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14846619.) (LEARDI, JOHN) (Entered: 11/03/2023)
11/03/2023	67	Notice of Request by Pro Hac Vice Alyssa M. Howard to receive Notices of Electronic Filings. (Pro Hac Vice fee $ 150 receipt number ANJDC-14846781.) (LEARDI, JOHN) (Entered: 11/03/2023)
11/06/2023		Pro Hac Vice counsel, MARGARET M. DOTZEL and ALYSSA M. HOWARD, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (kht) (Entered: 11/06/2023)
11/06/2023		Pro Hac Vice counsel, WILLIAM B. SCHULTZ, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (jal,) (Entered: 11/06/2023)
11/21/2023	68	ORDER granting 59 Motion for Leave to Appear Pro Hac Vice admission as to David A. Schulz. Signed by Magistrate Judge J. Brendan Day on 11/21/2023. (kht) (Entered: 11/21/2023)
11/21/2023	69	ORDER granting 54 Motion for Leave to Appear Pro Hac Vice, as to WENDY LIU. Signed by Magistrate Judge J. Brendan Day on 11/21/2023. (jdg) (Entered: 11/21/2023)
11/21/2023	70	ORDER granting 61 Motion for Leave to Appear Pro Hac Vice as to, Elizabeth Wydra, Brianne Gorod, and Nina Henry. Signed by Magistrate Judge J. Brendan Day on 11/21/2023. (jdg) (Entered: 11/21/2023)

11/22/2023		60 MOTION for Leave to File *Amicus Curiae Brief in Support of Defendants* no longer referred to the Magistrate Judge. Motion to be decided by the District Judge. (cry) (Entered: 11/22/2023)
11/22/2023		Reset Deadlines as to 60 MOTION for Leave to File *Amicus Curiae Brief in Support of Defendants*. Motion set for 12/4/2023 before Judge Zahid N. Quraishi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (cry) (Entered: 11/22/2023)
11/24/2023	71	REPLY to Response to Motion filed by JANSSEN PHARMACEUTICALS, INC. re 30 MOTION for Summary Judgment , 33 Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion* (CHIESA, JEFFREY) (Entered: 11/24/2023)
11/28/2023		Pro Hac Vice fee for WINDY LIU: $ 300, receipt number NEW49310 ($150 for 23-3818, $150 for 23-3335) (jr) (Entered: 11/28/2023)
11/28/2023		Pro Hac Vice fee received for David A. Schulz: $ 150, receipt number 135816 (jjc,) (Entered: 11/28/2023)
11/29/2023	72	Notice of Request by Pro Hac Vice David A. Schulz to receive Notices of Electronic Filings. (KOMUVES, FLAVIO) (Entered: 11/29/2023)
11/29/2023		Pro Hac Vice counsel, DAVID A. SCHULZ, has been added to receive Notices of Electronic Filing. Pursuant to L.Civ.R. 101.1, only local counsel are entitled to sign and file papers, enter appearances and receive payments on judgments, decrees or orders. (kht) (Entered: 11/29/2023)
12/06/2023	73	Letter from Defendants regarding consent request for extension of page limit. (Attachments: # 1 Text of Proposed Order)(COOGLE, CHRISTINE) (Entered: 12/06/2023)
12/07/2023	74	CONSENT ORDER that Defendants shall file a combined reply brief not to exceed 45 pages. Signed by Judge Zahid N. Quraishi on 12/7/2023. (kht) (Entered: 12/07/2023)
12/22/2023	75	REPLY to Response to Motion filed by All Defendants re 33 Cross MOTION for Summary Judgment *and Response to Plaintiff's Motion* (SVERDLOV, ALEXANDER) (Entered: 12/22/2023)
01/11/2024	76	TEXT ORDER granting 31 Motion to Appear Amicus Curiae; granting 34 Motion to Appear Amicus Curiae; granting 42 Motion to Appear Amicus Curiae; granting 43 Motion to Appear Amicus Curiae; granting 46 Motion to Appear Amicus Curiae; granting 48 Motion to Appear Amicus Curiae; granting 51 Motion for Leave to File; granting 55 Motion to Appear Amicus Curiae; granting 60 Motion for Leave to File Amicus Curiae Brief. Amicus Curiae shall file their proposed briefs within 7 days. So Ordered by Judge Zahid N. Quraishi on 01/11/2024. (Gonzalez, P) (Entered: 01/11/2024)
01/11/2024	77	BRIEF *OF ECONOMISTS AND SCHOLARS OF HEALTH POLICY AS AMICI CURIAE IN SUPPORT OF DEFENDANTS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS MOTION FOR SUMMARY JUDGMENT* (SHAH, JAMES) (Entered: 01/11/2024)
01/12/2024	78	BRIEF *OF AMICI CURIAE PUBLIC CITIZEN, PATIENTS FOR AFFORDABLE DRUGS NOW, DOCTORS FOR AMERICA, PROTECT OUR CARE, AND FAMILIES USA IN SUPPORT OF DEFENDANTS OPPOSITION TO PLAINTIFFS MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION* (MILZ, ANDREW) (Entered: 01/12/2024)

01/12/2024	79	BRIEF *of Amicus Curiae Abrams Institute for Freedom of Expression in Support of Defendants' Opposition to Plaintiff's Motion for Summary Judgment and Cross-Motion* (KOMUVES, FLAVIO) (Entered: 01/12/2024)
01/12/2024	80	BRIEF *OF AMICI CURIAE AARP AND AARP FOUNDATION SUPPORTING DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION* (SAVITS, GLEN) (Entered: 01/12/2024)
01/16/2024	81	BRIEF *of Amici Curiae American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, and American Society of Hematology* (GITOMER, MADELINE) (Entered: 01/16/2024)
01/17/2024	82	BRIEF *OF NATIONALLY RECOGNIZED HEALTHCARE AND MEDICARE EXPERTS AS AMICI CURIAE IN SUPPORT OF DEFENDANTS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS MOTIONS FOR SUMMARY JUDGMENT* (LEARDI, JOHN) (Entered: 01/17/2024)
01/17/2024	83	BRIEF *of Constitutional Accountability Center as Amicus Curiae in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment* (LEATHERS, DANIEL) (Entered: 01/17/2024)
01/18/2024		CLERK'S QUALITY CONTROL MESSAGE - The 77 Brief submitted by James C. Shah on 1/11/2024 contains an improper signature. Only the filing user is permitted to sign electronically filed documents with an s/. PLEASE RESUBMIT THE DOCUMENT WITH A PROPER ELECTRONIC SIGNATURE. This submission will remain on the docket unless otherwise ordered by the court. (jjc,) (Entered: 01/18/2024)
01/18/2024		CLERK'S QUALITY CONTROL MESSAGE - 81 Exhibit A filed by Madeline Gitomer on 1/16/2024 was submitted incorrectly as a BRIEF. PLEASE RESUBMIT the EXHIBIT USING the event EXHIBIT (to document). This submission will remain on the docket unless otherwise ordered by the court. (jjc,) (Entered: 01/18/2024)
01/19/2024	84	BRIEF *of Amici Curiae American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, and American Society of Hematology* (GITOMER, MADELINE) (Entered: 01/19/2024)
01/19/2024	85	Letter from Amici Curiae American Public Health Association, the American College of Physicians, the Society of General Internal Medicine, the American Geriatrics Society, and the American Society of Hematology re 81 Brief, 84 Brief. (GITOMER, MADELINE) (Entered: 01/19/2024)
02/07/2024	86	TEXT ORDER that the Court will conduct oral argument for the pending Motions for Summary Judgment in related cases 23-cv-3335, 23-cv-3818, 23-cv-14221, 23- cv-20814. Argument will be heard from the parties only. The Court has availability from 03/05/2024 through 03/08/2024 from 10:00 a.m. through 2:00 p.m. By 02/16/2024, counsel are to meet and confer and file a letter proposing: (1) dates for argument; and (2) a schedule for argument. So Ordered by Judge Zahid N. Quraishi on 2/7/2024. (kas) (Entered: 02/07/2024)
02/16/2024	87	Letter from Jeffrey S. Chiesa, Esq. to The Hon. Zahid N. Quraishi re: Oral Argument. (CHIESA, JEFFREY) (Entered: 02/16/2024)
02/20/2024	88	TEXT ORDER that the Court has reviewed the parties' letter regarding oral argument that was filed in 23-cv-3818 Janssen v. Becerra at ECF No. 87 . The Court adopts Plaintiffs' position. Oral argument for the four related matters (23-cv-3335, 23-cv-3818, 23-14221, and 23-20814) will be heard on 03/07/2024 beginning at 10:00 a.m., tentatively scheduled to conclude by 2:30 p.m. As previously noted, only the parties will be arguing. So Ordered by Judge Zahid N. Quraishi on 2/20/2024. (kas) (Entered: 02/20/2024)

02/29/2024	89	NOTICE of Appearance by HEATHER CARNEY COSTANZO on behalf of All Defendants (COSTANZO, HEATHER) (Entered: 02/29/2024)
03/04/2024	90	NOTICE of Appearance by CASSANDRA SNYDER on behalf of All Defendants (SNYDER, CASSANDRA) (Entered: 03/04/2024)
03/04/2024	91	NOTICE by All Defendants *of Supplemental Persuasive Authority* (Attachments: # 1 Exhibit A - AstraZeneca Opinion)(SNYDER, CASSANDRA) (Entered: 03/04/2024)
03/04/2024	92	NOTICE of Appearance by BRIAN DAVID NETTER on behalf of All Defendants (NETTER, BRIAN) (Entered: 03/04/2024)
03/05/2024	93	MOTION for Leave to Appear Amicus Curiae by Alliance for Aging Research. (Attachments: # 1 Memorandum in Support, # 2 Proposed Amicus Brief, # 3 Text of Proposed Order)(BALDINI, STEPHEN) (Entered: 03/05/2024)
03/06/2024	94	TEXT ORDER granting 93 Motion to Appear Amicus Curiae. Amicus Curiae shall file their proposed briefs within 7 days. SO Ordered by Judge Zahid N. Quraishi on 3/6/2024. (kas) (Entered: 03/06/2024)
03/07/2024	95	BRIEF *of Amicus Curiae Alliance for Aging Research* (BALDINI, STEPHEN) (Entered: 03/07/2024)
03/07/2024	96	Minute Entry for proceedings held before Judge Zahid N. Quraishi: Oral Argument on Motion for Summary Judgment 30 and Cross-Motion for Summary Judgment 33 in 23-3818 heard with related cases, 23-20814 MSJ 28 and Cross- MSJ 37 , 23-3335 MSJ 36 and Cross-MSJ 38 and 23-14221 MSJ 18 and Cross- MSJ 24 held on 3/7/2024. Court Reserves Decision. (Court Reporter, Megan McKay-Soule (609-815-2319) (kas,) (Entered: 03/07/2024)
03/14/2024	97	Transcript of Oral Argument held on 3/7/2024, before Judge Judge ZAHID N. QURAISHI. Court Reporter/Transcriber Megan McKay-Soule (609-815-2319). **NOTICE REGARDING (1) REDACTION OF PERSONAL IDENTIFIERS IN TRANSCRIPTS AND (2) MOTION TO REDACT AND SEAL:** The parties have seven (7) calendar days to file with the Court a Notice of Intent to Request Redaction of this Transcript to comply with Fed.R.Civ.P.5.2(a) (personal identifiers). Parties seeking to redact and seal this Transcript, or portions thereof, pursuant to L.Civ.R. 5.3(g) must e-file a Motion to Redact and Seal utilizing the event `Redact and Seal Transcript/Digital Recording`. Redaction Request to Court Reporter/Transcription Agency due, but not filed, by 4/4/2024. Redacted Transcript Deadline set for 4/15/2024. Release of Transcript Restriction set for 6/12/2024. (jal,) (Entered: 03/14/2024)
04/29/2024	98	OPINION filed. Signed by Judge Zahid N. Quraishi on 4/29/2024. (jdg) (Entered: 04/29/2024)
04/29/2024	99	ORDER that Defendants' 33 Motion for Summary Judgment is GRANTED. Plaintiff's 30 Motion for Summary Judgment is DENIED. The Clerk is directed to mark this matter as CLOSED. Signed by Judge Zahid N. Quraishi on 4/29/2024. (jdg,) (Entered: 04/29/2024)
04/30/2024	100	NOTICE OF APPEAL as to 98 Opinion, 99 Order on Motion for Summary Judgment, by JANSSEN PHARMACEUTICALS, INC.. Filing fee $ 605, receipt number ANJDC-15328254. The Clerk's Office hereby certifies the record and the docket sheet available through ECF to be the certified list in lieu of the record and/or the certified copy of the docket entries. Appeal Record due by 6/28/2024. (Attachments: # 1 Certificate of Service)(CHIESA, JEFFREY) (Entered: 04/30/2024)

05/06/2024	101	USCA Case Number 24-1821 for 100 Notice of Appeal (USCA), filed by JANSSEN PHARMACEUTICALS, INC.. USCA Case Manager Stephanie (Document Restricted - Court Only) (ca3sb,) (Entered: 05/06/2024)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

JANSSEN PHARMACEUTICALS, INC.,
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
200 Independence Ave, SW
Washington, DC 20201;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Ave, SW
Washington, DC 20201;

CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of Centers for Medicare & Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244; *and*

CENTERS FOR MEDICARE AND MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

Civil Action No. _____

COMPLAINT

1. Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen") brings this action to stop innovation-damaging congressional overreach that threatens the United States'

primacy in developing transformative therapies and in patients' access to those treatments. Specifically, Janssen seeks relief from the unconstitutional Medicare "Drug Price Negotiation Program" ("Program") established by the Inflation Reduction Act ("IRA" or "Act"), Pub. L. No. 117-169, §§ 11001–11004, 136 Stat. 1818, 1833–64 (2022) (codified in part at 42 U.S.C. §§ 1320f to 1320f-7).

2. For decades, federal law has supported a research and development ecosystem that has made the United States the world leader in pharmaceutical innovation. Under that system, drugs that achieve commercial success after extensive scientific development enable the creation of next-generation pioneering medicines that change the way we fight diseases. Janssen has made this patient-driven innovation the cornerstone of its business. It invests tremendous resources in developing transformative medicines that address unmet medical needs and seeking cures to previously untreatable diseases such as cancers, autoimmune conditions, cardiovascular disease, HIV, and depression. Since 2016, Janssen has invested more than $65 billion in research and development, resulting in Food and Drug Administration ("FDA") approvals for eight new medications and 52 expanded indications or new formulations for existing medications.

3. The U.S. innovation ecosystem to which Janssen contributes has two vital components, both of which are severely threatened by the Program. The first is the bargain at the heart of the patent and regulatory laws: when companies invest in and secure FDA approval for new treatments, they receive time-limited and constitutionally safeguarded protections, including the exclusive rights to make and

sell the new treatment. The second is the operation of free-market forces to establish prices for medicines during and after their patent terms. Together, these components strongly encourage risk-taking and innovation to facilitate future breakthroughs. As a result of that system, patients have faster and broader access to pioneering treatments in the United States than in any other country.

4. The Act replaces this self-sustaining cycle with a coercive scheme that, if fully implemented, will deal a fatal blow to both vital components of the innovation ecosystem. That scheme forces manufacturers to relinquish their patented drugs on draconian terms dictated by the Government and retroactively rescinds the bargained-for patent and regulatory exclusivity protections that fuel innovation. The Act also supplants the free-market system with punitive price controls, granting a Government agency nearly unlimited authority to set drug prices at arbitrary amounts untethered to the value of those medications to patients. Those radical changes will impede development of new treatments and result in reduced drug availability and fewer treatment options in the U.S. healthcare market.

5. Tacitly admitting its unconstitutional overreach, Congress cloaked the Program in deceptive terms. According to the Act, manufacturers voluntarily "agree" to "negotiate" so-called "fair" prices for each drug selected for the Program. In truth, those labels are nothing more than rhetorically appealing falsehoods: there is no genuine agreement, no real negotiation, and nothing fair about the price the Government unilaterally dictates.

6. A real negotiation produces a binding contract only when both parties freely agree on its terms—especially price. Yet the Program's "negotiations" result in the Government agency that selects the drugs for the Program unilaterally setting the price it will pay. That price, by statute, must be well below a drug's market value. And the Act both empowers and encourages the Government to lower that automatic price ceiling even further, without any lower limit (all the way down to $0).

7. Nor is participation in the Program voluntary. The Government has gone to great lengths to mislead the public on that point, doubling down on "voluntariness" rhetoric in its final guidance and related statements to generate a carefully crafted smokescreen.

8. Under the Act, a manufacturer may only escape from the Program's mandates and penalties by withdrawing *all* of its products from Medicare and Medicaid—not just the drug selected for the Program. That provision is the legal equivalent of a gun to the head because it would require the manufacturer to give up access to nearly 40% of the U.S. health-care market. That step would immediately deprive the manufacturer of revenues required to fuel research and development of new drugs, while also jeopardizing the manufacturer's ability to innovate, compete, and operate in the future. Even more fundamentally, forcing withdrawal from Medicare and Medicaid would cause millions of patients to lose insurance for and thus access to the manufacturer's drugs they have come to depend on.

9. Manufacturers who remain in Medicare and Medicaid are subject to crippling penalties if they do not submit to the Government's terms: a tax of 186% to

1900% of a selected drug's daily domestic revenues until the manufacturer "agrees" to participate in the supposedly voluntary Program. Those penalties are so coercive that no manufacturer would ever willingly incur them, a point Congress conceded when it projected that the penalty provisions would not raise a single dollar in revenue.

10. The end result is that manufacturers must: (1) submit to the Program's deprivation of constitutionally protected property rights in a selected drug; (2) incur crippling penalties for failing to "agree" with those terms; or (3) withdraw their entire portfolio of treatments from Medicare and Medicaid. That purported choice is no choice at all.

11. The Act's innovation-damaging scheme is unconstitutional as applied to Janssen in at least three ways:

12. *First*, the Program inflicts an uncompensated physical taking of Xarelto®, a widely prescribed medication manufactured and marketed by Janssen that treats blood clots and reduces the risk of stroke. The Program forces Janssen to provide "access" to Xarelto® products on terms set by the Government, and to which Janssen would never voluntarily agree. The Program thus forces a transfer of Janssen's property to third parties, appropriating Janssen's rights to possess and dispose of the medicines it invests billions to develop. This constitutional violation is doubly problematic because the Program targets Xarelto® as a *patented* drug, and those patents confer additional property rights by providing an entitlement to market exclusivity.

13. Stripped of its misleading labels, the Program is a straightforward confiscation of constitutionally protected property. It is akin to the Government taking your car on terms that you would never voluntarily accept and threatening to also take your house if you do not "agree" that the taking was "fair." The Program employs a statutory access requirement rather than a tow truck, but its effect is the same: Janssen has no choice but to surrender its Xarelto® products to Medicare on Government-dictated terms that fail to provide just compensation and undermine Janssen's long-term ability to continue its innovative business of delivering transformational medicines to patients.

14. *Second*, by coercing Janssen to "agree" with the Government that it is "negotiating" a "fair" price, the Program compels Janssen to make false and misleading statements in violation of the First Amendment. Congress passed the Act based upon the false narrative that it created a negotiation process for drug prices. While the Government may choose to deceptively describe the Program as involving an "agreement" to "negotiate" a "fair" price, it cannot force manufacturers to echo its misleading messaging.

15. *Third*, the Act would violate Janssen's constitutional rights even if participation in the Program were voluntary (it is not), by impermissibly conditioning Janssen's overall participation in Medicare and Medicaid on compliance with the Program's terms and the resulting deprivation of Janssen's property and speech rights. That condition is unconstitutional because it is grossly disproportionate to Janssen's total participation in Medicare and Medicaid.

16. The Act's ultimate harm is to patients. It deprives tomorrow's patients of innovative medicines made possible by protected patent rights and market-based pricing, and the future generics enabled solely by today's innovator drugs. And it harms today's patients by threatening access to existing therapies and eviscerating incentives to continually improve those therapies. Janssen brings this action to stop the Act's violation of its property and speech rights and to safeguard its ability to continue developing the pioneering treatments that patients depend on.

PARTIES

17. Plaintiff Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

18. Janssen manufactures and sells Xarelto® (rivaroxaban), a medication that treats and helps prevent blood clots and reduces the risk of stroke. Xarelto® belongs to a category of medications known as direct oral anticoagulants, which represent a significant therapeutic advancement over earlier anticoagulants. Janssen is the exclusive U.S. licensee of the patents that claim rivaroxaban and its use, and has the exclusive right to market Xarelto® products in the United States.

19. Defendant Xavier Becerra is the Secretary of Health and Human Services. Secretary Becerra is charged by statute with administering the Social Security Act, including Medicare, Medicaid, and the Program at issue here. Secretary Becerra is sued in his official capacity.

20. Defendant U.S. Department of Health and Human Services ("HHS") is a cabinet-level department of the United States Government.

21. Defendant Chiquita Brooks-LaSure is the Administrator of the Centers for Medicare and Medicaid Services. Administrator Brooks-LaSure is sued in her official capacity.

22. Defendant Centers for Medicare and Medicaid Services ("CMS") is an agency of the United States Government within HHS. HHS has delegated the Secretary's authority to administer Medicare, Medicaid, and the Program to CMS.

JURISDICTION AND VENUE

23. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the laws of the United States, including the United States Constitution.

24. This Court also has subject-matter jurisdiction under 28 U.S.C. § 1346(a) because the United States is a Defendant, and because the United States has waived its sovereign immunity regarding suits for declaratory and injunctive relief, *see* 5 U.S.C. § 702.

25. This Court may award declaratory relief pursuant to 28 U.S.C. §§ 2201–02, as well as any other equitable relief it deems appropriate under its inherent powers.

26. Venue is proper under 28 U.S.C. § 1391(e)(1) because Defendants are officers acting in their official capacities and corresponding agencies of the United States, and Janssen's corporate headquarters is located in New Jersey.

27. Xarelto® is among the ten most widely reimbursed drugs for Medicare Part D patients, meaning that it will be subject to the Program beginning in September 2023.[1]

FACTUAL ALLEGATIONS

A. The Pharmaceutical Innovation Ecosystem

28. Patented prescription drugs like Xarelto® are the product of a complex innovation ecosystem that involves significant research and investment by Janssen.

29. Janssen invests billions of dollars each year to develop new drugs that help patients live longer, healthier lives. In 2022 alone, Janssen's investment totaled $11.6 billion. Janssen has dedicated more than $65 billion to research and development since 2016.[2]

30. These investments have made it possible for Janssen to provide dozens of medications, including Xarelto®, to Medicare and Medicaid patients. Since 2016, Janssen has secured FDA approval for eight new medications and 52 additional FDA approvals for expanded indications and/or new product formulations—several of which were for innovative forms of Xarelto®.

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[1] *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026*, § 30.3 (June. 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf ("*Revised Guidance*") ("CMS *will select* for negotiation the 10 … highest ranked negotiation-eligible drugs remaining on the ranked list for initial price applicability year 2026." (emphasis added)).

[2] *See* Janssen, *U.S. Pricing Transparency Brief* 2 (2022), https://transparencyreport.janssen.com/.

31. The United States healthcare market is the global leader in pharmaceutical development due to an innovation ecosystem that has two key components.

32. The first is a critical bargain at the heart of the patent and regulatory laws: when a manufacturer invests in and secures FDA approval for a new treatment, the manufacturer receives time-limited legal protections for the new treatment. These protections include the exclusive rights to manufacture and market the treatment. *See, e.g.*, *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 135 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention."); *Am. Securit Co. v. Shatterproof Glass Co.*, 268 F.2d 769, 777 (3d Cir. 1959) (patents "grant" the owner "the exclusive right to manufacture, use[,] and sell the invention which is disclosed").

33. The second is the operation of the free market to set prices for medicines during and after their patent terms. Under this framework, manufacturers negotiate the prices for their patented drug products with other market participants, such as private insurance plans and their agents. Federal law then bases the amount Medicare and Medicaid pay for the drugs on those free-market negotiations. *See* ¶¶ 51–52, *infra*. This commitment to market-based pricing is so important that when Congress created the Medicare prescription drug benefit program, it expressly *prohibited* federal agencies from "interfer[ing] with the negotiations between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding the prices for covered drugs. 42 U.S.C. § 1395w-111(i).

34. Together, those two components incentivize manufacturers to make the investments necessary to develop transformative new treatments. The end result is a self-sustaining cycle of innovation in which successful drugs generate the revenues necessary to fund next-generation medicines. That incentive structure yields significant benefits for patients: Studies show that new treatments are available much sooner, and much more broadly, in the United States than in other countries.[3] Another critical benefit of this system is that participants in clinical trials gain access to new research treatments before they are widely available and help others by contributing to medical research.

35. These incentives are necessary because developing a new prescription drug is expensive, time-consuming, and rife with failure.

36. The process of developing a new drug and securing FDA approval costs $2.6 *billion* on average, and often takes 10 to 15 years or longer from start to finish.[4]

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[3] *See, e.g.*, Doug Badger, Galen Inst., *Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control Over Pricing and Restrictions on Access* 15 (2019), https://galen.org/assets/Badger-Report-March-2019.pdf; Pharmaceutical Research and Manufacturers of America ("PhRMA"), *Global Access to New Medicines Report* 8, 11–26 (2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/2023-04-20-PhRMA-Global-Access-to-New-Medicines-Report-FINAL-1.pdf.

[4] Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion* (Nov. 18, 2014), https://f.hubspotusercontent10.net/hubfs/9468915/TuftsCSDD_June2021/pdf/pr-coststudy.pdf; *see also* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016) (similar); PhRMA, *Research & Development Policy Framework* (Sept. 2021), https://phrma.org/en/policy-issues/Research-and-Development-Policy-Framework.

37. The failure rate for new drugs is also exceptionally high. The initial development stage often involves screening hundreds of thousands of investigational compounds. Only 0.5% of drugs that enter preclinical testing are tested in human trials.[5] And as few as 12% of compounds that reach clinical trials ultimately receive FDA approval.[6] The end result is that only 0.02% of drugs that enter preclinical testing will ever reach patients.[7]

38. Even after an approved drug reaches the market, around 20–30% of new drugs recoup the investment necessary to bring them to market.[8]

39. As a result, development of new medicines depends on market-based revenues from the small fraction of clinical compounds that ultimately become commercially successful drugs. As one recent study explained, the small fraction "of successful projects that result in new commercialized drugs have to provide enough revenue to justify the investment" in the large number of "failed compounds."[9]

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[5] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1299137/pdf/5-7400236.pdf.

[6] DiMasi et al., *supra* note 4; Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 16–17 (2021), https://www.cbo.gov/publication/57126.

[7] Kraljevic et al., *supra* note 5, at 837.

[8] *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7, 11 (AEI 2008), https://www.aei.org/wp-content/uploads/2014/07/-pharmaceutical-price-regulation-public-perceptions_113401853979.pdf ("[O]nly three out of ten marketed drugs earn back their investments."); John A. Vernon et al., *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010), https://pubmed.ncbi.nlm.nih.gov/19655335/ (finding only 20% of new drugs attain revenues that exceed average R&D costs).

[9] Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med. 1, 4–5 (2016), https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-

40. The Act would upend both components of the self-sustaining innovation ecosystem, jeopardizing manufacturers' ability to develop new medicines and improve existing treatments. As described below, the Program supplants the market-based pricing framework with Government-dictated price controls, and also retroactively rescinds the longstanding bargain for patent and regulatory exclusivities by directing CMS to adopt artificially low prices that annihilate the value of manufacturers' exclusive right to market their patented medicines. *See* ¶¶ 70–71, *infra*.

41. The Program undermines the innovation ecosystem in other ways as well. For example, the Program strongly disincentivizes continued investment in development of new indications for and formulations of medicines following their initial FDA approval. Post-approval development, which can result in treatments becoming available to new patient populations, has created a substantial benefit for cancer patients and pediatric patients, among others.[10] But the Program will sharply curtail development of new indications for and formulations of existing medicines because these innovations will often immediately become subject to the Program's

4; *see also* Joe Kennedy, Info. Tech. & Innovation Found., *The Link Between Drug Prices and Research on the Next Generation of Cures* 6 (2019), https://www2.itif.org/2019-drug-prices-cures.pdf.

[10] *See, e.g.*, Partnership for Health Analytic Research, *Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines* 12 (2023), https://www.pharllc.com/publication/implications-of-the-ira-price-setting-provisions-on-post-approval-indications-for-small-molecule-medicines/ (finding that 61% of small-molecule oncology medicines approved between 2006 and 2012 received at least one post-approval indication, and that nearly half of those post-approval indications were awarded more than seven years after initial approval).

automatic price ceilings. Manufacturers are thus left with no time to recoup the investments necessary to develop them.[11]

42. Xarelto® demonstrates the impact of post-approval innovations that will be lost in the future due to the Program's restrictive scheme. FDA first approved Xarelto® in 2011. Janssen's subsequent research and development have resulted in multiple additional FDA approvals for Xarelto® since 2018. These post-approval innovations include: a lower 2.5 mg strength to treat patients with chronic coronary artery disease or peripheral artery disease in 2018; a new indication to help prevent blood clots in acutely ill medical patients in 2019; an expanded peripheral artery disease indication in 2021; and two new pediatric indications and a new oral suspension formulation in 2021. But the Program's aggregation methodology—in which CMS treats all medicines with the same active moiety as a single drug—subjects these recently approved medicines to the Program's price controls now because a different Xarelto® product was first approved more than seven years ago.

43. Drug manufacturers have already begun to shift R&D investment priorities, portfolios, and budgets in response to the Program's limits on

[11] This disincentive results from (1) the statutory rule that a drug becomes eligible for the Program seven years after it is first approved, and (2) CMS's decision to aggregate "all dosage forms and strengths of [a] drug with the same active moiety and the same holder of a New Drug Application" when determining which drugs are subject to the Program. *See Revised Guidance*, *supra*, § 30.1 ("CMS will identify a potential qualifying single source drug [for drug products] using … all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." (citations omitted)).

manufacturers' ability to benefit from the innovation they create.[12] For example, one study estimates that Government-dictated price caps will "reduce overall annual cancer R&D spending by about $18.1 billion, or 31.8%."[13]

44. By undermining constitutionally protected property rights and incentives to develop new drugs, the Program will eventually result in fewer new treatment options for doctors and patients.

45. And because today's branded pharmaceuticals become tomorrow's generics, the Program also threatens to limit generic entry, and therefore patient access to reduced cost generics and biosimilars, in the future. Nine out of every ten prescriptions dispensed in the United States are for generic versions of branded

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[12] *See, e.g.*, Josh Nathan-Kazis, *Novartis CEO: Some Cancer Drugs Dropped From Pipeline Because of Medicare Price Negotiations*, Barron's (May 19, 2023), https://www.barrons.com/articles/novartis-stock-price-ceo-cancer-drug-medicare-e9b0fcb7; James Waldron, *Bristol Myers CEO Already Reassessing Portfolio in Wake of US Pricing Law: Report*, Fierce Biotech (Nov. 21, 2022), https://www.fiercebiotech.com/biotech/bristol-myers-already-reassessing-portfolio-wake-ira-ceo-tells-ft (Act will result in cancellation of some development programs and adversely affect "investment in clinical research, especially in areas like oncology that require significant investment following initial FDA approval"); Max Gelman, *Updated: Eli Lilly Blames Biden's IRA for Cancer Drug Discontinuation as the New Pharma Playbook Takes Shape*, Endpoint News (Nov. 1, 2022), https://endpts.com/eli-lilly-rolls-snake-eyes-as-it-axes-two-early-stage-drugs-including-a-40m-cancer-therapy-from-fosun/ (identifying two drug-development programs cancelled in light of Act's restrictive terms).

[13] Tomas J. Philipson et al., *Policy Brief: The Impact of Recent White House Proposals on Cancer Research* 1 (June 2022), https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2022/06/Cancer-Policy-Brief-June-27-no-tracking.pdf; *see also* Stephen J. Ubi, *Biden Promised a "War on Cancer"—But Declared War on the Cure Instead*, STAT (July 6, 2023), https://www.statnews.com/2023/07/06/biden-cancer-moonshot-ira-intellectual-property/.

drugs,[14] meaning that 10% of prescriptions for innovative medicines drive the entire pharmaceutical industry. By sharply curtailing the incentives to develop new innovative treatments, the Program will create unmet healthcare needs rather than reduce them.

B. Statutory and Regulatory Background

Medicare and Medicaid Dominate the U.S. Health Care Industry

46. The Program directly governs Medicare drug pricing, but it will also have significant effects on drug pricing and patient access for participants in Medicaid, the 340B Drug Pricing Program, and private plans.

47. Medicare provides health insurance coverage for millions of Americans ages 65 and above, as well as persons with long-term disabilities. *See* 42 U.S.C. §§ 1395–1395*lll*.

48. Medicaid provides health insurance coverage for low-income Americans. *See id.* §§ 1396–1396w-7.

49. The 340B drug pricing program requires manufacturers to provide discounts for covered outpatient drugs for qualifying health care organizations that care for uninsured and low-income patients. *See id.* § 256b.

50. In 2021, Medicare accounted for 21% of total U.S. health-care expenditures, while Medicaid accounted for another 17%.[15]

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[14] Association for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* (2021), https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[15] CMS, *NHE Fact Sheet*, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet (updated June 14, 2023).

51. Medicare Part B provides health-insurance benefits for physician-administered drugs, among other things. Under Medicare Part B, the Federal Government reimburses providers for a portion of the costs of those medications, using an "average sales price" model that incorporates the discounts negotiated by private health plans and other market participants.

52. Medicare Part D provides health-insurance benefits for self-administered prescription drugs. Under Medicare Part D, the Federal Government reimburses sponsors of private health insurance plans for a portion of the costs of such drugs. In turn, plan sponsors pay manufacturers for covered drugs. Historically, the Government under Medicare Part D has received the benefit of drug prices negotiated in the free market, based on rebates provided by drug manufacturers.

53. Under the Medicaid prescription drug rebate program, manufacturers enter into rebate agreements with the Secretary of HHS.

54. As explained below, the Act radically changes Medicare's long-established public-private partnership model, with significant spillover implications for Medicaid, the 340B program, and the private payer market. *See, e.g.*, 42 U.S.C. § 1396r-8(c)(1) (tying rebates under the Medicaid drug rebate program to the average price paid by wholesalers and retail pharmacies, which will in turn be influenced by the maximum price dictated under the Program).[16]

[16] *See also, e.g.*, Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/ (observing that

55. Moreover, there will be additional spillover effects in the commercial market, given that the "maximum fair price" will be publicly released and therefore available to be leveraged by plans in commercial market negotiations with manufacturers. Previously, pricing information in certain government programs has been protected as proprietary and highly confidential.

The Inflation Reduction Act's Sham "Negotiation" Program for Prescription Drugs

56. The Act directs the Secretary of HHS to implement what the Act deceptively describes as a "Drug Price Negotiation Program." *Id.* § 1320f(a).

57. According to the Act, the Program involves three basic steps: (1) CMS selects a group of drugs each year for participation in the Program, (2) each manufacturer of a selected drug must then sign an "agreement" to "negotiate" with CMS regarding the price Medicare will pay for the drug, and (3) the negotiations will result in CMS adopting a "maximum fair price" for the drug. *See id.* §§ 1320f-1(a), 1320f-2(a)(1)-(3), 1320f-3(a)(1), 1320f-4(a).

58. CMS has doubled down on Congress's deceptive labels, repeatedly stating in a recent guidance document that CMS will "negotiate with" manufacturers to select a "maximum fair price" for each selected drug, and likewise repeatedly characterizing that process as "voluntary."[17] CMS similarly asserted in a press release that the Program allows the Government "to directly negotiate the prices of

changes to Medicare drug prices "could have implications for Medicaid rebates and ultimately Medicaid drug spending by changing drug list prices").

[17] *E.g.*, *Revised Guidance*, *supra*, §§ 40.1, 40.6.

covered prescription drugs" with manufacturers.[18] CMS Administrator Brooks-LaSure likewise told a news outlet that "this is a voluntary process for manufacturers to negotiate with us directly."[19]

59. In reality, the Program is far from a "negotiation."

60. In the first year of the Program, CMS must select ten of the highest-reimbursed Part D drugs for participation in the Program by September 1, 2023. *See* 42 U.S.C. §§ 1320f(d)(1), 1320f-1(a)(1). Once CMS selects a drug, its manufacturer then has until October 1, 2023, to sign an "agreement" to "negotiate" with CMS regarding the maximum price Medicare will pay for the drug. *Id.* §§ 1320(a), (b), (d)(2)(A), 1320f-2. CMS unilaterally dictates the terms of this purported agreement, which it has presented to manufacturers on a take-it-or-leave-it basis.[20]

61. Contrary to the Act's false labels, the Program does not rest on a genuine agreement to participate, because the Government has given manufacturers no real choice but to sign the Manufacturer Agreement and shoulder the obligations associated with it. If a manufacturer refuses to sign this "agreement" to "negotiate," it must pay an excise tax penalty on *every* domestic sale of the selected drug, starting

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[18] CMS, *CMS Releases Revised Guidance for Historic Medicare Drug Price Negotiation Program* (June 30, 2023), https://www.cms.gov/newsroom/press-releases/cms-releases-revised-guidance-historic-medicare-drug-price-negotiation-program.

[19] Michael Erman & Patrick Wingrove, *U.S. Will Allow Drugmakers to Discuss Medicare Drug Price Negotiations*, Reuters (June 30, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/us-issues-revised-guidance-medicare-drug-price-negotiation-2023-06-30/.

[20] *See* CMS, *Medicare Drug Price Negotiation Program Agreement* (July 3, 2023) ("Manufacturer Agreement"), https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf.

at 186% of the drug's daily U.S. revenues and escalating to 1900% of those revenues. *See* 26 U.S.C. § 5000D(d).[21] In many instances, that requirement would amount to millions of dollars in penalties starting the *very next day* after a manufacturer fails to sign an agreement.

62. Those penalties are so draconian that no manufacturer would ever willingly incur them. Indeed, Congress recognized that manufacturers have no choice but to comply when it estimated that nearly identical penalty provisions in a precursor bill to the IRA would generate "no revenue."[22]

63. The only way a manufacturer can avoid this penalty (aside from acquiescing to the Government's demands) is if the manufacturer withdraws its products from both Medicare and Medicaid. The required withdrawal is not limited to the product selected for "negotiation," but extends to *all* of the manufacturer's products, including those not chosen for "negotiation" and those excluded from "negotiation" by statute. *See* 26 U.S.C. § 5000D(c). Not only is this punishment wholly unconnected and disproportionate to a manufacturer's decision to not "negotiate" over a single Medicare drug, but it would result in the manufacturer

[21] *See also* Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)*, at 4, tbl. 2 (2022), https://crsreports.congress.gov/product/pdf/R/R47202 (explaining how the tax rates are computed).

[22] Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions Of Title XIII – Committee On Ways And Means, of H.R. 5376, The 'Build Back Better Act,' As Passed by The House of Representatives: Fiscal Years 2022–2031*, at 8 (Nov. 19, 2021), https://www.jct.gov/publications/2021/jcx-46-21/; *see also* Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, at 10 (2023), https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf ("CBO expects that drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower, negotiated prices.").

losing access to nearly 40% of the U.S. health-care market. As the Third Circuit recently observed, "[t]he federal government dominates the healthcare market," "pay[ing] for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023) (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022)).

64. By withdrawing, a manufacturer would immediately lose access to critical revenue needed to research and develop new treatments, and the economic effects of this withdrawal would compound over time, jeopardizing the manufacturer's ability to innovate, compete, or successfully operate over the long term. Critically, withdrawal would also harm the vulnerable patient populations who have come to rely on the manufacturer's medicines through Medicare and Medicaid.

65. That all-or-nothing approach has far-reaching effects because manufacturers often provide many products to patients through Medicare and Medicaid. Janssen alone has Medicare Part D and Medicaid agreements for dozens of products, including treatments for autoimmune conditions (such as rheumatoid arthritis), cancer, cardiovascular disease, depression, and HIV. As a result, Janssen could not avoid the Act's penalties without depriving Medicare and Medicaid patients of access to these medications.

66. In short, when the Government selects a manufacturer's drug for the Program, the manufacturer faces the following purported alternatives: (1) sign the Manufacturer Agreement to negotiate, which as explained below will deprive the manufacturer of constitutionally-protected property rights and market-based pricing

for the selected drug; (2) incur crippling penalties for failing to "agree" to that deprivation; or (3) withdraw its portfolio of treatments from Medicare and Medicaid entirely. The Government has persisted in telling the public that manufacturers have the "optio[n]" of choosing among these crippling outcomes, and that participation in the Program is "voluntary." *Revised Guidance*, *supra*, § 40.1. But it is clear that the Program was specifically designed with only one outcome in mind: forced participation in the Program on terms a manufacturer cannot refuse.

67. After a manufacturer is forced to sign the Manufacturer Agreement, the coercion continues. For example, manufacturers of drugs selected for 2026 must submit detailed and highly sensitive confidential business information to CMS by October 2, 2023. 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2)(A). In addition, manufacturers must "compl[y] with" any other "requirements determined by the Secretary to be necessary for purposes of administering the [P]rogram and monitoring compliance with the [P]rogram," with no apparent limit on what those obligations could be. *Id.* §§ 1320f-2(a)(5). The Act imposes a civil monetary penalty of $1 million "for each day" a manufacturer fails to comply with these mandates. *Id.* § 1320f-6(c); *see also Revised Guidance*, *supra*, § 100.2.

68. CMS has taken this authority a step further, asserting that it *also* has the right to unilaterally "amend" those obligations as it deems "necessary" at any time *after* the manufacturer signs the agreement.[23] In other words, CMS will force manufacturers to not only submit to its terms, but to also concede that CMS can

[23] Manufacturer Agreement, *supra*, §§ II(e), IV(b).

change those terms whenever it chooses. To call that one-sided process an "agreement" strains the English language past the breaking point.

69. Nor does the Program involve an actual negotiation. The Act uses this terminology, with CMS making an initial so-called "offer" and the manufacturer making a "counteroffer." 42 U.S.C. § 1320f-3(b)(2)(B)–(D). But behind these empty words looms the coercive reality: a manufacturer that does not agree to the price CMS imposes must either shoulder the excise tax penalty or withdraw *all* its products from Medicare and Medicaid entirely. *See* 26 U.S.C. § 5000D(a); *see also Revised Guidance*, *supra*, § 60.4.4. Like the supposedly voluntary Manufacturer Agreement, this "negotiation" is designed to end only one way: with the Government unilaterally dictating a price. *See* 42 U.S.C. § 1320f-3(b)(2)(E).

70. According to the Act, the Program's "negotiations" are also supposed to yield a "maximum fair price" for the selected drug. Yet the Program intentionally jettisons market forces and drives the price well below what is objectively fair. For example, the Act requires the price to be *at least* 25% below the average price paid by non-federal wholesalers and retail pharmacies. *Id.* § 1320f-3(c)(3)(A). That automatic discount increases to 35% for "extended monopoly" drugs that have been approved for 12 to 16 years, and 60% for "long monopoly" drugs that have been approved for more than 16 years. *Id.* § 1320f-3(c)(3)(C), (c)(4)–(5).

71. The Act further exacerbates that departure from market-based pricing by directing CMS—the same agency that pays for the drugs—to "achieve the lowest maximum fair price for each selected drug" below those statutory ceilings. *Id.*

§ 1320f-3(b)(1). The Act empowers CMS to drive the prices down, without limit, based on CMS's own vested interest in obtaining artificially low prices. Indeed, because the Act does not prescribe a pricing floor (with one exception not relevant here), CMS could seek to adopt a $0 price for a selected drug, regardless of the drug's market value or entitlement to market exclusivity under the patent laws and related statutes and regulations.

72. Once CMS has picked its price, it must publish the so-called "maximum fair price" for the drug, along with an "explanation" for that price. *Id.* §§ 1320f(d)(6), 1320f-4(a). This price ceiling will then become effective on January 1, 2026.

73. After this price goes into effect, the manufacturer is obligated—under threats of additional civil monetary penalties *ten times* the difference between the price charged and the Government-dictated price, *id.* § 1320f-6d(a)—to grant hospitals, physicians, and other Medicare participants "access" to the selected drug on the Act's one-sided terms. *Id.* §§ 1320f-2(a). That access obligation continues indefinitely, and can thus remain in place for years, until "the Secretary determines" that a generic version of the drug is "approved" and "marketed." *Id.* § 1320f-1(c)(1).

The Imminent Selection of Xarelto® for the Program

74. The Act requires the Secretary to select ten "negotiation-eligible" drugs by September 1, 2023. *Id.* § 1320f-1(a)(1).

75. The Act defines a "negotiation-eligible" drug for 2026 and 2027 as a "qualifying single source drug" that is "among the 50 qualifying single source drugs with the highest total expenditures" under Medicare Part D. *Id.* § 1320f-1(d)(1)(A).

76. In turn, a "qualifying single source drug" includes covered Part D drugs that have been approved by FDA and on the market for at least seven years, subject to various exceptions not relevant here. *Id.* § 1320f-1(e)(1)(A); *see also* 21 U.S.C. § 355.

77. Based on these criteria, Xarelto® will be "negotiation eligible" for the 2026 initial price applicability year.

78. According to CMS's implementing guidance, the agency will select the top 10 drugs that account for the highest Medicare spending.[24]

79. Xarelto® falls within this group and thus will be selected for the 2026 initial price applicability year.[25]

80. Because Xarelto® was first approved by FDA in 2011, it will be classified as a "short monopoly" drug under the Program, with CMS required by statute to select a "maximum fair price" that is *at least* 25% below market value. *See* 42 U.S.C. § 1320f-3(c)(3)–(5).[26] Together with the other provisions described above, this requirement rescinds the bargain at the heart of the patent and regulatory laws and replaces it with a radical new price-control scheme that deprives Janssen of its constitutionally protected speech rights and property rights in Xarelto® products.

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[24] *Revised Guidance*, *supra*, § 30.3.

[25] *See also* Sean Dickson & Inmaculada Hernandez, *Drugs Likely Subject to Medicare Negotiation, 2026-2028*, 29 J. Mgmt. Care Spec. Pharm. 229, 229 (Mar. 2023), https://www.jmcp.org/doi/epdf/10.18553/jmcp.2023.29.3.229?role=tab (stating that Xarelto® is "expected to be" selected for initial price applicability year 2026).

81. CMS has admonished manufacturers to begin taking action now, before the agency publishes the list of selected drugs, given the extensive requirements associated with participation in the Program. For example, the *Revised Guidance* issued on June 30, 2023 states that "manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture will be included on the selected drug list."[27]

C. The Act Violates Janssen's Constitutional Rights

82. The Program violates Janssen's constitutional rights in at least three respects.

83. *First*, the Program will appropriate Janssen's patented Xarelto® products for third-party use without providing adequate compensation, a clear physical taking in violation of the Fifth Amendment.

84. *Second*, the Program will violate the First Amendment by compelling Janssen to make false and misleading statements through the Manufacturer Agreement, including that the Program will involve "negotiating" a "fair" price for Xarelto® products.

85. *Third*, the Act would violate Janssen's constitutional rights even if participation in the Program were voluntary (it is not), by impermissibly conditioning Janssen's ability to participate in Medicare and Medicaid on Janssen's relinquishing its speech and property rights.

[27] *Revised Guidance*, *supra*, at 9.

The Program Effects a Physical Taking of Janssen's Patented Xarelto® Products

86. The Fifth Amendment prohibits the Government from taking private property without compensating the owner for the full and fair value of that property.

87. This protection "preserve[s] freedom and empowers persons to shape and to plan their own destiny in a world where governments are always eager to do so for them." *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021) (cleaned up). "[P]eople … do not expect their property, real or personal, to be actually occupied or taken away" without being compensated for it. *Horne v. Dep't of Agric.*, 576 U.S. 350, 361 (2015).

88. The Government has a categorical duty to compensate the owner of personal property when it "appropriates" the owner's rights in that property "for the enjoyment of third parties." *Cedar Point Nursery*, 141 S. Ct. at 2072. Rights protected by this principle include the "right to exclude," *id.*, the "right of access," *id.*, and "the rights to possess, use and dispose of" the property, *Horne*, 576 U.S. at 361–62 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) (cleaned up)).

89. For example, a physical taking occurs when a law or regulation "requires physical surrender" of personal property, with "the [owner] los[ing] any right to control [its] disposition." *Id.* at 364.

90. Janssen's Xarelto® products are personal property protected by the Fifth Amendment's Takings Clause. *See Horne*, 576 U.S. at 358. As a result, the Government may not take those products without providing just compensation.

91. Janssen's property rights are reinforced by the Xarelto® patents, which confer an additional "right to exclude others from making, using or vending [the] invention." *Talbot v. Quaker-State Oil Refin. Co.*, 104 F.2d 967, 968 (3d Cir. 1939) (quoting *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 35–37 (1923)); *see also* 35 U.S.C. § 154(a)(1).

92. Federal law further protects Janssen's Xarelto® products by granting additional and distinct regulatory exclusivity rights. These protections apply in a variety of circumstances, including when a drug receives initial or supplemental FDA approval (e.g., for a new pediatric use studied at the Government's request). *See* 21 U.S.C. §§ 355(c)(3)(E), 355(j)(5)(F), 355A. These provisions afford additional periods of market exclusivity for approved Xarelto® products, creating a key incentive for Janssen to pursue additional innovations that enhance patient outcomes.

93. The Program effects a physical taking of Janssen's Xarelto® products because it strips Janssen of its rights to possess and control the disposition of those products and forces their transfer to third parties on the Government's terms, over Janssen's objection. *See Horne*, 576 U.S. at 2429; *Cedar Point Nursery*, 141 S. Ct. at 2072.

94. This physical taking stems from the Act's statutory "access" requirement and the so-called Manufacturer Agreement that implements the access requirement. *See* 42 U.S.C. § 1320f-2. Specifically, the Act requires manufacturers, as part of their "agreement" with the Government, to "provid[e]" eligible beneficiaries

(and their hospitals, doctors, providers, and suppliers) "access to" drugs selected for participation in the Program. *Id.* § 1320f-2(a)(3).

95. This obligation, which binds Janssen before the sham "negotiations" even begin, appropriates Janssen's property rights in its Xarelto® products by transferring Janssen's rights to possess and dispose of these products to third parties—thus effecting a physical taking. *See Cedar Point Nursery*, 141 S. Ct. at 2072; *Horne*, 576 U.S. at 361–62.

96. The Act's promise that Janssen can receive a highly discounted, Government-dictated price in exchange for the appropriated property does not change the takings analysis. "[W]hen there has been a physical appropriation, [courts] do not ask whether it deprives the owner of all economically valuable use of the item taken." *Horne,* 576 U.S. at 363 (cleaned up). Instead, "any payment from the Government in connection with that action goes, at most, to the question of just compensation." *Id.* at 364; *accord Cedar Point Nursery*, 141 S. Ct. at 2074. Thus, the "maximum fair price" bears on the amount of compensation due, not the threshold question whether the Program inflicts a taking.

97. At most, an arbitrary and artificially low price cap is simply a limitation on third parties' right of access. A limitation restricting access "for up to four 30-day periods in one calendar year" did not call into question the physical taking in *Cedar Point Nursery*. *See* 141 S. Ct. at 2069, 2074–75. The same principle applies here. That the Act "authorizes only limited … access" (here, access on terms unilaterally

imposed by the Government) "does not transform [the Program] from a physical taking into a use restriction." *Id.* at 2075.

98. The Manufacturer Agreement, with its property-stripping obligations, is not the result of Janssen "voluntarily participat[ing] in a price-regulated program or activity." *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). Rather, the Program compels Janssen to sign the agreement to avoid crushing tax penalties, and then coerces continued compliance with the agreement's terms under threat of additional monetary penalties.

99. After Xarelto® is selected in September 2023 for the 2026 initial price applicability year, Janssen must sign the Manufacturer Agreement by October 1, 2023, and thus give up core property rights in its Xarelto® products. Failing to do so would make Janssen liable for a penalty on *every* domestic sale of Xarelto® (including sales outside Medicare and Medicaid), starting at 186% of each sale and ballooning to as much as 1900% until Janssen relinquishes its property rights. *See* 26 U.S.C. § 5000D. Given the widespread use of Xarelto® in the market, this penalty would quickly reach extraordinary levels.

100. The statute purports to offer a third option, but it is illusory. Specifically, the Act suggests that manufacturers can avoid the penalties described above by withdrawing their entire product portfolio *not just* from Medicare but also from Medicaid as well. *Id.* § 5000D(c). But that is not a viable option for several reasons.

101. *First*, no rational manufacturer can pull out of a market that accounts for "almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis*, 58 F.4th at 699. Doing so would deprive the manufacturer of funds needed for research and development of new medications in the near term, and would eventually prevent the manufacturer from competing successfully in the marketplace in the long-term. More fundamentally, Medicaid and Medicare patients would suffer the loss of access to critical medicines they rely upon today.

102. *Second*, even if Janssen could terminate all of its existing Medicare and Medicaid agreements and forgo access to nearly half of the Nation's health-care market to the detriment of millions of patients, the Act delays a manufacturer's withdrawal such that the manufacturer would *still* be subjected to the Act's penalties. *See, e.g.*, 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). CMS has sought to circumvent this doubling up of adverse consequences by adopting, through guidance, an expedited protocol for termination of a manufacturer's Medicare and Medicaid agreements. *See Revised Guidance*, *supra*, §§ 40.1, 40.6. That protocol seeks to treat withdrawals initiated by manufacturers, which are subject to a statutory 11- to 23-month delay before taking effect, as withdrawals by the Government, which are subject to a 30- or 60-day delay. *See id.*; 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i)-(ii); 1396r–8(b)(4)(B)(i). CMS does not explain how its protocol complies with these statutory requirements, and no explanation is apparent. Even if CMS has authority to manipulate the statutory text in that fashion, CMS's attempt to reverse course tacitly acknowledges

the weakness in the Government's position and makes the agency's gamesmanship readily apparent.

103. The Act, by design, dictates one and only one outcome: the forced transfer of a drug manufacturer's property on the Government's terms. Janssen's supposed alternatives are a crushing penalty on every domestic sale of Xarelto® or a loss of access to nearly half of the U.S. health-care market for all of the company's products. This impossible situation amounts to a "gun to the head" that gives Janssen no choice "but to acquiesce" and sign away its rights. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581–82 (2012) ("*NFIB*"); *see also Union Pac. R. Co. v. Pub. Serv. Comm'n of Mo.*, 248 U.S. 67, 70 (1918) (government cannot "impose an unconstitutional burden" on private parties "by the threat of penalties … and then … declare the acceptance [of that burden] voluntary").

104. Should a manufacturer acquiesce, additional civil monetary penalties compel continued compliance with the Program's terms. The Program imposes these penalties at ten times the amount a manufacturer charges over the "maximum fair price." 42 U.S.C. § 1320f-6(a). This is yet another "gun to the head" to cement the forced transfer of property to and appropriated right of access for third parties. *NFIB*, 567 U.S. at 581.

The Program Compels Speech in Violation of the First Amendment

105. The Act compels manufacturers like Janssen to endorse the false narrative that they "agre[e]" to a "negotiat[ion]" that results in a "fair" price. 42 U.S.C. § 1320f-2(a), (a)(1).

106. More specifically, the Act requires the manufacturer of a selected drug to enter into an "agreement" with the Secretary, under which the manufacturer will be statutorily bound to "negotiate" what the Act refers to as a "fair" price for the selected drug. *Id.* Moreover, due to the structure of the Program, a manufacturer must "agree" to accept the Government-dictated price before the "negotiation" has even begun, at a time when the manufacturer does not know what price the Government will impose. As CMS has made clear, by signing the Manufacturer Agreement and accompanying addendum, "the Manufacturer agrees" that it will "negotiate to determine … a maximum fair price," that it later will "have engaged in negotiation," that the resulting price was "negotiated," and that it "agree[s]" the price is "fair."[28]

107. Those statements are speech governed by the First Amendment.

108. Those statements are compelled, false, and misleading.

109. The Manufacturer Agreement to participate in the Program is not voluntary, but instead consists of Government-dictated terms that manufacturers have no real choice but to accept. Opting out of the Program is not, in fact, an option given the grossly disproportionate impact of doing so on a manufacturer's entire drug portfolio or the crushing tax penalties that would apply—penalties so onerous that Congress acknowledged no company would willingly endure them.

110. Similarly, the process that follows after a manufacturer signs the Manufacturer Agreement is not a "negotiation" because the Government has

[28] Manufacturer Agreement, *supra*, § V, add.

authority to unilaterally pick the price it will pay. The manufacturer must accept the Government's decision or else shoulder immense penalties for failing to acquiesce.

111. Compounding these problems, the "maximum fair price[s]" established under the Program bear none of the traditional hallmarks of fairness. The prices are not set through proceedings before a neutral arbiter, but rather are imposed by the same agency that pays for the selected drugs. CMS has also claimed authority to unilaterally alter the terms of the negotiation and subject manufacturers to a daily $1,000,000 penalty for noncompliance with any new or modified requirements it chooses to impose.[29] Further, while courts have long held that "fair market value" is the proper metric for determining the value of property protected by the Fifth Amendment (such as patented drug products), *Horne*, 576 U.S. at 368–70, the Act disregards market forces and instead mandates that the Government-dictated prices be at least 25% below the average price paid by non-federal wholesalers and retail pharmacies.

112. For those reasons, Janssen strongly *disagrees* that the "maximum fair price[s]" are "fair" and the result of "negotiation."

113. By coercing manufacturers to signal their "agreement" with the Government's preferred rhetoric, the Act improperly turns Janssen into a "vehicle for spreading a message with which it disagrees." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 17 (1986).

[29] Manufacturer Agreement, *supra*, §§ II(e), IV(b).

114. As the Supreme Court has recognized, requiring private entities to follow "a [G]overnment-drafted script" necessarily "'alters the content'" of constitutionally protected speech. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371 (2018) (quoting *Riley v. Nat'l Fed'n of Blind, Inc.*, 487 U.S. 781, 795, (1988)). The Government may choose to deceptively describe the Program as involving an "agreement" to "negotiate" a "fair" price, but it cannot force manufacturers to be its messengers.

115. CMS has attempted to fend off First Amendment challenges through sleight of hand by including a disclaimer in the Manufacturer Agreement. According to CMS, a manufacturer signing the Agreement "does not make any statement regarding or endorsement of CMS' views."[30] This obscure provision buried in the fourth section of the agreement cannot overcome the singular message communicated by the Act and every other provision in the Manufacturer Agreement. Regardless of what CMS's self-serving disclaimer says, a manufacturer's signature will convey that the manufacturer has "agree[d]" to "negotiate" a "fair" price. Indeed, this disclaimer provision—which CMS alone has drafted and will present to manufacturers on a take-it-or-leave-it basis—is nothing more than another exercise of CMS's coercive powers to compel additional speech, using the same threat of immense penalties and economic loss to force a manufacturer to "agree" with the Government's litigating position.

[30] Manufacturer Agreement, *supra*, § IV(f).

116. Based on the selection criteria for "negotiation-eligible" drugs, Janssen will be compelled to sign the Manufacturer Agreement by October 1, 2023, creating an obligation for Janssen to "negotiate" a "maximum fair price" for Xarelto®. Under that Agreement, the Government will establish the price by August 1, 2024, and require Janssen to provide access to its Xarelto® products at that price beginning in 2026.

The Program Unconstitutionally Conditions Participation in Medicare and Medicaid on Janssen's Relinquishment of Constitutional Rights

117. The Government cannot shield the Program from constitutional scrutiny by asserting that participation is voluntary. The Act was specifically designed to force manufacturers' compliance without true alternatives. But even if that were not the case, the Act would still violate Janssen's rights by imposing an unconstitutional condition on Janssen's participation in Medicare and Medicaid.

118. "[T]he unconstitutional conditions doctrine … vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). Accordingly, "the government may not deny a benefit to a person because he exercises a constitutional right." *Id.* (quoting *Regan v. Taxation With Representation of Wash.*, 461 U.S. 540, 545 (1983)).

119. That doctrine applies even when a person has no right to participate in a Government-sponsored program. *See Perry v. Sindermann*, 408 U.S. 593, 597 (1972). Were it otherwise, the Government would be able to "penaliz[e] and inhibi[t]"

the "exercise of [constitutional] freedoms," "produc[ing] a result which it could not command directly." *Id.* at 597 (cleaned up).

120. In the property-rights context, conditioning participation in a government program is unconstitutional if (1) directly imposing the condition would result in a taking, and (2) there is no "nexus" or "rough proportionality" between the condition and the program participation sought. *Koontz*, 570 U.S. at 605–06; *Dolan v. City of Tigard*, 512 U.S. 374, 386 (1994); *Loretto*, 458 U.S. at 439 n.17 (right to use one's own "property may not be conditioned on [the owner] forfeiting the right to compensation for a physical occupation").

121. In the speech context, "freedom of speech prohibits the government from telling people what they must say." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013) (cleaned up). The Government therefore cannot "compel" parties who wish to participate in a program "to adopt a particular belief as a condition of" doing so. *Id.* at 218–19; *see also W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 641–42 (1943).

122. To the extent the Program is voluntary (it is not), compliance with the Program is a condition of Janssen's participation not just in Medicare but also Medicaid: to continue to market *any* of its products through Medicare and Medicaid without incurring massive tax penalties, Janssen must comply with the Program's requirements for the single product being "negotiated." *See* 26 U.S.C. § 5000D(c).

123. That condition is unconstitutional: The Program coerces Janssen into relinquishing its property rights, and it imposes a condition on both Medicare and

Medicaid participation that is grossly disproportionate to the Government's interest in lowering the price of a single Medicare drug.

124. *First*, the Program effectuates a physical taking of Janssen's patented Xarelto® products, as alleged above. *See* ¶¶ 86–104, *supra*.

125. *Second*, the Program achieves its goals through coercive means. *See Koontz*, 570 U.S. at 604; ¶¶ 56–73, *supra*. If Janssen does not comply with the Program's requirements, the Government will impose a daily penalty starting at 186% of every domestic sale. To avoid that penalty, Janssen would have to forgo access to nearly half of the U.S. health-care market. No rational drug manufacturer would take that step given the serious adverse effect it would have on the manufacturer's long-term ability to innovate and compete, and the harm Medicare and Medicaid patients would experience. Both of those approaches amount to "economic dragooning that leav[e] [Janssen] with no real option but to acquiesce" to the Program's property-stripping demands. *NFIB*, 567 U.S. at 582.

126. The condition is even more coercive because, as explained above, Janssen's revenues from Medicare and Medicaid are integral to its research and development efforts to develop the lifesaving drugs of tomorrow.

127. *Third*, the Program's all-or-nothing approach is grossly disproportionate. *See Dolan*, 512 U.S. at 386. Had the Program's punitive terms extended only to Janssen's ability to market Xarelto® through Medicare, proportionality would have been a closer question. But under the Act, Janssen will not be able to provide *any* of its products through Medicare or Medicaid unless it

relinquishes core property rights in *one* selected drug for the Medicare program. And the Program's adverse impact on *existing* Medicare and Medicaid agreements despite its purported focus on *future* drug prices only exacerbates this imbalance.

128. The condition imposed by the Program is also unconstitutional because it forces manufacturers to give up their free-speech rights by "agreeing" to endorse the fiction that the Program involves a "negotiation" to establish a "fair" price. *See Agency for Int'l Dev.*, 570 U.S. at 218–19. The Government cannot "deman[d] that [manufacturers] adopt—as their own—the Government's view" of the Program as a condition of participating in Medicare and Medicaid. *Id.* at 218.

CLAIMS

Count I
Physical Taking of Personal Property (Fifth Amendment)

129. Janssen re-alleges and incorporates by reference paragraphs 1 through 128 as if fully set forth herein.

130. The Fifth Amendment prohibits the Government from taking personal property without just compensation.

131. Janssen's Xarelto® products are personal property protected by the Fifth Amendment.

132. As applied to Janssen, the Program effects a physical taking of the company's Xarelto® products. Janssen will be required, under threat of a massive penalty on every domestic sale of a Xarelto® product or a total loss of both Medicare and Medicaid participation, to sign the Manufacturer Agreement. That Agreement by statute will then force Janssen, over its objection and under the threat of

additional civil monetary penalties, to provide Medicare participants access to its Xarelto® products. Through these coercive obligations, the Government forces Janssen to transfer its products to third parties and appropriates Janssen's rights to possess and dispose of its personal property.

133. The Program provides for a Government-dictated "maximum fair price" in return for this coerced right of access—a price that by statute must be significantly below the drug's market value, and therefore by definition cannot satisfy the Government's constitutional duty to provide just compensation.

134. Janssen seeks only declaratory relief with respect to its physical takings claim. Such relief is appropriate here because it would "avoi[d] … the burden of numerous suits at law between" Janssen and the Government regarding each instance of a taking of a Xarelto® product, which would present issues that "are substantially the same." *PhRMA v. Williams*, 64 F.4th 932, 943 (8th Cir. 2023) (citation, alteration, and quotation marks omitted); *Di Giovanni v. Camden Fire Ins. Ass'n*, 296 U.S. 64, 70 (1935).

135. Without declaratory relief, Janssen "would be bound to litigate a multiplicity of suits to be compensated" in a manner that would not provide "complete, practical and efficient" relief. *Williams*, 64 F.4th at 945 (citation and quotation marks omitted); *see also Terrace v. Thompson*, 263 U.S. 197, 214 (1923). Instead, declaratory relief would "(1) clarify and settle legal relations in issue and (2) terminate and afford greater relief from the uncertainty, insecurity, and controversy

giving rise to present action." *Gruntal & Co. v. Steinberg*, 854 F. Supp. 324, 333 (D.N.J. 1994) (cleaned up).

136. Declaratory relief is also appropriate because repeated inverse condemnation suits "would entail an utterly pointless" back-and-forth, where "every dollar" taken from Janssen would "generate a dollar of … compensation." *E. Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality opinion).

137. Most fundamentally, the Court should grant declaratory relief because Janssen's injuries cannot be adequately compensated through a legal remedy. Patented drug products, including Xarelto®, play a crucial role in Janssen's innovation ecosystem that is impossible to quantify, replace, or replicate, and the Program's effects will spill over into non-Medicare markets in ways that are equally significant and impossible to quantify. It follows that the physical taking of Janssen's Xarelto® products is "bound to result in many present and future damages of such nature as to be difficult, if not incapable of, measurement." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 585 (1952).

138. Xarelto® is a unique drug with no competing generics, patented precisely because it is useful, novel, and nonobvious. *See* 35 U.S.C. §§ 102–03. Those unique characteristics "mak[e] damages an inadequate remedy" because no dollar amount can fully compensate for what is, in reality, irreplaceable. *Ramirez de Arellano v. Weinberger*, 745 F.2d 1500, 1527–28 (D.C. Cir. 1984), *vacated on other grounds*, 471 U.S. 1113 (1985).

139. The Court should therefore declare that the Program effects a physical taking of Janssen's Xarelto® products.

Count II
Compelled Speech (First Amendment)

140. Janssen re-alleges and incorporates by reference paragraphs 1 through 139 as if fully set forth herein.

141. The First Amendment protects the right to refrain from speaking. *Becerra*, 138 S. Ct. at 2371.

142. The Act compels Janssen to state in writing that it will reach "agreement" with the Government on a "fair" price through a process of "negotiation," 42 U.S.C. § 1320f–2(a), when in fact the prices imposed through the Program are unfair, the negotiation is a sham, and the agreement is coerced.

143. Laws compelling speech are presumptively unconstitutional unless the Government can demonstrate that they are necessary to serve a compelling interest. *Becerra*, 138 S. Ct. at 2371.

144. The Government has no legitimate interest in forcing Janssen to convey its misleading message regarding the nature of the Program and its sham "negotiations." As a result, the Act violates Janssen's First Amendment rights.

145. Because such violations of the First Amendment "unquestionably constitut[e] irreparable injury," an injunction is warranted. *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

146. The Court should declare that the Act's requirements that manufacturers "agree" to "negotiate" "maximum fair prices," 42 U.S.C. § 1320f-

2(a)(1), are unconstitutional and enjoin Defendants from enforcing those requirements.

147. More specifically, the Court should enjoin Defendants from forcing Janssen to sign the Manufacturer Agreement to "negotiate" a "maximum fair price" for Xarelto®.

148. The Court should also enjoin Defendants from requiring Janssen to "agree" that the Government-dictated price is "fair."

149. If the Government unconstitutionally coerces Janssen into signing the Manufacturer Agreement before the Court has an opportunity to rule on the merits of this suit, the Court should declare that the Agreement is unlawful and enjoin the Government from enforcing its terms, including any penalties provided for under the Act.

Count III
Unconstitutional Condition on Medicare and Medicaid Participation
(First and Fifth Amendments)

150. Janssen re-alleges and incorporates by reference paragraphs 1 through 149 as if fully set forth herein.

151. The Government cannot condition a benefit on the relinquishment of constitutional rights.

152. The Act's coercive structure makes clear that there is no way manufacturers can avoid the Program's requirements. But the Act would violate Janssen's constitutional rights even if the Program were voluntary, by impermissibly conditioning Janssen's participation in Medicare and Medicaid on compliance with the Program's terms. The Government may not force Janssen to surrender core

property rights in its Xarelto® products in order to continue participating in Medicare and Medicaid.

153. This condition is coercive because its acceptance is compelled by a massive penalty on every domestic sale of a Xarelto® product or complete withdrawal from both Medicare and Medicaid. The condition is also disproportionate because it makes Janssen's ability to provide *all* of its pharmaceutical products' through Medicare and Medicaid—not just the selected drug—contingent on the price for a single drug, and because it applies to existing agreements despite a goal of lowering future prices.

154. The Act also unconstitutionally conditions participation in Medicare and Medicaid on Janssen endorsing the false narrative that it "agrees" to "negotiate" Government-dictated prices, and that such prices are "fair."

155. To the extent the Court concludes that the Program is voluntary, the Court should declare that the Act imposes an unconstitutional condition on Medicare and Medicaid participation, and enjoin Defendants from enforcing that condition and imposing penalties for noncompliance therewith.

PRAYER FOR RELIEF

WHEREFORE, Janssen respectfully requests that the Court issue judgment in its favor and against Defendants and grant the following relief:

A. Declare that the Program effects an uncompensated physical taking in violation of the Fifth Amendment.

B. Declare that the Program compels speech in violation of the First Amendment.

C. Declare that the Act unconstitutionally conditions participation in Medicare and Medicaid on the relinquishment of Janssen's property and free-speech rights.

D. Declare that any agreements Janssen may have been forced to sign in connection with the Program are null and void.

E. Enjoin Defendants from forcing Janssen to sign the Manufacturer Agreement, imposing penalties for non-compliance with the Program's requirements, and enforcing any further agreements Janssen may have been forced to sign in connection with the Program.

F. Award reasonable attorneys' fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and

G. Grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ David A. Luttinger, Jr.

David A. Luttinger, Jr.
S. Conrad Scott (*pro hac vice* application forthcoming)
COVINGTON & BURLING LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
(212) 841-1134
dluttinger@cov.com
cscott@cov.com

Robert A. Long, Jr. (*pro hac vice* application forthcoming)
Kevin F. King (*pro hac vice* application forthcoming)
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001-4956
(202) 662-6000
rlong@cov.com
kking@cov.com

Counsel for Plaintiff

July 18, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

JANSSEN PHARMACEUTICALS, INC., *Plaintiff*, v. XAVIER BECERRA, Secretary of Health and Human Services, *et al.*, *Defendants*.	Civil Action No. 23-cv-03818-ZNQ-JBD

DECLARATION OF JEFFREY S. CHIESA IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I, Jeffrey S. Chiesa, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am an attorney at Chiesa Shahinian & Giantomasi PC and counsel for Plaintiff Janssen Pharmaceuticals, Inc. I have personal knowledge of the facts set forth in this declaration.

2. Attached as **Exhibit A** is a true and correct copy of a document issued on June 30, 2023, by the Centers for Medicare and Medicaid Services ("CMS") entitled "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026." This document was accessed via CMS's website on

August 16, 2023, at https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

3. Attached as **Exhibit B** is a true and correct copy of the "Medicare Drug Price Negotiation Program Agreement," issued by CMS and accessed via CMS's website on August 16, 2023, at https://www.cms.gov/inflation-reduction-actand-medicare/medicare-drug-price-negotiation.

4. Attached as **Exhibit C** is a true and correct copy of a study published by Sean Dickson and Dr. Inmaculada Hernandez in March 2023 in Volume 29, Issue 3 of the Journal of Managed Care & Special Pharmacy, entitled "Drugs Likely Subject to Medicare Negotiation, 2026–2028." This document was accessed on August 16, 2023, at https://www.jmcp.org/doi/epdf/10.18553/jmcp.2023.29.3.229?role=tab.

5. Attached as **Exhibit D** is a true and correct copy of the Congressional Research Service report entitled "Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)," updated on August 10, 2022. This document was accessed on August 16, 2023, at https://crsreports.congress.gov/product/pdf/R/R47202.

6. Attached as **Exhibit E** is a true and correct copy of the Joint Committee on Taxation November 2021 publication entitled "Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The 'Build Back Better Act,' As Passed By The House of Representatives: Fiscal

Years 2022–2031." This document was accessed on August 16, 2023, at https://www.jct.gov/publications/2021/jcx-46-21/.

7. Attached as **Exhibit F** is a true and correct copy of the Congressional Budget Office 2022 publication entitled "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act." This document was accessed on August 16, 2023, at https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.

8. Attached as **Exhibit G** is a true and correct excerpt of testimony given by CMS Administrator Brooks-LaSure before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health, on April 26, 2023. This document was accessed on August 16, 2023, at https://docs.house.gov/meetings/IF/IF14/20230426/115801/HHRG-118-IF14-Wstate-Brooks-LaSureC-20230426.pdf.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 16, 2023

s/ Jeffrey S. Chiesa

Jeffrey S. Chiesa
CHIESA SHAHINIAN & GIANTOMASI PC
105 Eisenhower Parkway
Roseland, NJ 07068
(973) 530-2050
jchiesa@csglaw.com

Counsel for Plaintiff
Janssen Pharmaceuticals, Inc.

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: June 30, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026

This memorandum provides interested parties with the revised Medicare Drug Price Negotiation Program guidance for initial price applicability year 2026. It includes four sections:

A. An introduction, which begins on page 1.
B. A summary of changes and clarifications to the initial memorandum released on March 15, 2023, which begins on page 2.
C. A summary of the public comments received in response to the initial memorandum, and the Centers for Medicare & Medicaid Services' (CMS') responses, which begins on page 8.
D. Revised guidance that establishes final policies on the topics discussed for initial price applicability year 2026, which begins on page 92 and for which a table of contents appears on page 94.

CMS may supplement this guidance with further program instruction to explain how these policies will be implemented during initial price applicability year 2026 (e.g., technical instructions for data submissions).

A. Introduction

Sections 11001(c) and 11002(c) of the Inflation Reduction Act (IRA) direct the Secretary to implement the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, on March 15, 2023, CMS issued an initial memorandum for implementation of the Negotiation Program for initial price applicability year 2026. CMS also voluntarily solicited comments on a number of key aspects of the initial memorandum. The 30-day comment period for the initial memorandum began March 15, 2023 and concluded April 14, 2023. CMS received more than 7,500 comment letters in response to the initial memorandum, representing a wide range of views from academic experts and thought leaders, consumer and patient organizations, data vendors/software technology entities, health plans, health care providers, health systems, individuals, labor unions, pharmaceutical and biotechnology

manufacturers, pharmacies, pharmacy benefit managers (PBMs), state governments, trade associations, venture capital firms, and wholesalers.

CMS will make public copies of the timely comment letters that CMS received on the Inflation Reduction Act website at https://www.cms.gov/inflation-reduction-act-and-medicare in July 2023. Comment letters from individuals not representing organizations will have the name, address, and contact information of the individual removed for privacy purposes. Additionally, substantively duplicative letters (e.g., submitted as part of a coordinated advocacy campaign) will be combined into a single document.

After consideration of the comments received, CMS is making certain changes to the policies described in the initial memorandum in this revised guidance for initial price applicability year 2026. These comments also may be considered in development of program guidance for initial price applicability years 2027 or 2028 of the Negotiation Program, for which CMS also intends to solicit comments. CMS will develop its policies for 2029 and all subsequent initial price applicability years of the Negotiation Program through notice-and-comment rulemaking. The public will have an additional opportunity to submit comments as part of that rulemaking process, and comments submitted in response to the initial memorandum may be considered as part of that rulemaking process.

CMS is providing a summary of significant comments that it received in response to the initial memorandum, as well as the agency's response to those significant comments, which begins on page 8. CMS is not responding in this document to all 7,500 comments that it received, but instead is addressing those significant comments that have prompted a revision or a clarification of its policies under the Negotiation Program, or that otherwise raised a significant issue warranting a response that would explain to the public the agency's resolution of that question.

B. Summary of Changes and Clarifications in Revised Medicare Negotiation Guidance

CMS received many constructive, thoughtful, and helpful comments from consumer and patient groups, manufacturers, pharmacies, individuals, and other interested parties on the initial Medicare Drug Price Negotiation Program Guidance that was released on March 15, 2023. This section provides a summary of the key changes and clarifications made to the initial memorandum based on these comments and other feedback. CMS provides responses to the comments received in section C of this revised guidance and has made corresponding changes and clarifications to the policies described in the initial memorandum, as summarized below.

Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2026: In section 30 of this revised guidance, CMS has made clarifications to policies detailed in section 30 of the initial memorandum, including:

- Bona Fide Marketing of a Generic Drug: CMS has clarified in section 30.1 of this revised guidance the process it will use to determine if bona fide marketing of a generic drug or biosimilar competitor to a potential qualifying single source drug is occurring for the purposes of drug selection. CMS will review both Prescription Drug Event (PDE) data and Average Manufacturer Price (AMP) data reported by manufacturers. The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be based on a totality of the circumstances, including PDE and AMP data.

- Orphan Drug Exclusion: CMS has clarified in section 30.1.1 of this revised guidance that a drug that has designations from the U.S. Food and Drug Administration (FDA) for more than one rare disease or condition will not qualify for the Orphan Drug Exclusion, even if the drug has not been approved for any indications for the additional rare disease(s) or condition(s) and that CMS will only consider active designations and active approvals when evaluating a drug for the Orphan Drug Exclusion; that is, CMS will not consider withdrawn orphan designations or withdrawn approvals as disqualifying a drug from the Orphan Drug Exclusion. CMS does not have the statutory authority to change the starting date from which qualifying single source drug status is determined, regardless of whether the drug or biological product was previously eligible for the Orphan Drug Exclusion under 1192(e)(3)(A) of the Social Security Act ("the Act").
- Exception for Small Biotech Drugs and Biosimilar Delay: CMS has clarified in sections 30.2.1 and 30.3.1 of this revised guidance the scope of the data that CMS will use to calculate the Small Biotech Drug Exception, which patents and litigation will be considered related to the Biosimilar Delay determination and how CMS will evaluate the manufacturing schedule for the marketing of the Biosimilar, as well as how, for both the Small Biotech Exception and the Biosimilar Delay, CMS will protect information from disclosure and communicate to the public whether there were successful requests.

Section 40 – Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026: CMS has made the following changes and clarifications to policies detailed in section 40 of the initial memorandum:

- Manufacturer Negotiation Agreement: CMS revised section 40.1 to establish a process for a Primary Manufacturer that is unwilling to enter into an Agreement for the Negotiation Program to expedite its termination from the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program. The revised guidance also specifies that a Primary Manufacturer may terminate its Agreement with CMS at any time, provided the conditions for termination are met, as described in section 40.6 of this revised guidance.
- Data Submission, Confidentiality, and Data Use Provisions: CMS revised section 40.2.2 of the guidance to state that CMS will not publicly discuss ongoing negotiations prior to the release of the explanation of the maximum fair price (MFP) unless a Primary Manufacturer publicly discloses information regarding the negotiation process. Primary Manufacturers may choose to publicly disclose information regarding ongoing negotiations at its discretion. In addition, CMS will treat as proprietary certain data submitted by a Primary Manufacturer of a selected drug in accordance with sections 1194(e)(1) and 1194(e)(2) of the Act, but if a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary. CMS removed the data destruction requirements under the confidentiality policy pertaining to Primary Manufacturers in section 40.2.2 of this revised guidance. Section 40.2.3 of the revised guidance also provides that CMS will provide the Primary Manufacturer an opportunity for corrective action in the event a submission is incomplete or inaccurate.
- Public Explanation of MFP: CMS will publish a public explanation of the MFP for initial price applicability year 2026 for each selected drug by March 1, 2025 that will include a narrative explanation of the negotiation process, the agreed-upon MFP, and redacted

information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable.

- Use of Medicare Transaction Facilitator (MTF): CMS clarified in section 40.4 of this revised guidance that it intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to help effectuate access to the MFP through a retrospective refund model. CMS is also exploring allowing the use of a standardized refund amount from the manufacturers to the pharmacies under a retrospective refund model and confirms it will require the use of a 14-day prompt pay standard for the refund from manufacturers to pharmacies and other dispensing entities to reimburse dispensing entities for passing through the MFP.
- Suggestion of Error: CMS clarified in section 40.5 of this revised guidance that if a Primary Manufacturer in good faith believes that CMS has made an error in the calculation of the ceiling or the computation of MFP across dosage forms and strengths, the Primary Manufacturer can submit a suggestion of error. CMS will respond to suggested errors within 30 days.
- Manufacturer Ownership Transfer of Selected Drugs: CMS clarified in section 40.7 of this revised guidance the Primary Manufacturer's ongoing responsibilities if the Primary Manufacturer of a selected drug transfers ownership of one or more New Drug Application(s) (NDA) / Biologics License Application(s) (BLA) of the selected drug to another entity, unless and until the Primary Manufacturer transfers all the NDAs / BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer as evidenced by a novation that meets certain criteria.

Section 50 – Negotiation Factors: In the revised guidance, CMS reaffirmed that it will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. CMS also clarified that, for initial price applicability year 2026, it will review cost-effectiveness measures and studies that use such measures to determine whether the measure used may be considered in accordance with section 1194(e)(2) of the Act. However, while such measures may be considered, they will not be used to adjust the initial offer if the measure does not provide relevant information or is not permitted in accordance with section 1194(e)(2) of the Act and section 1182(e) of the Act. CMS has also noted that outcomes such as changes to productivity, independence, and quality of life will be considered when these outcomes correspond with a direct impact on the individuals taking the selected drug or therapeutic alternative(s) and are permitted by section 1194(e)(2) of the Act.

Section 60 – Negotiation Process: CMS has revised the guidance to provide additional detail about how CMS will use the days' supply field in PDE data to calculate a 30-day equivalent supply using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) when calculating the MFP ceiling (described in section 60.2 of this revised guidance) and using the Wholesale Acquisition Cost (WAC) ratio to apply the MFP across dosage forms and strengths (described in section 60.5 of this revised guidance). As described in section 60.3.2 of this revised guidance, when comparing prices of therapeutic alternatives for purposes of informing a starting price for the initial offer, CMS may use an alternative methodology for calculating a 30-day equivalent

supply when appropriate. In addition, the following revisions were made in this section of the guidance:

- Limitations on Offer Amount: CMS has revised section 60.2 of this revised guidance to use the single ceiling per 30-day equivalent supply across all dosage forms and strengths of the selected drug. CMS has also clarified that the time period for determining whether a selected drug is an extended- or long-monopoly drug runs from NDA approval to the start of the applicable initial price applicability year and clarified that PDE units will be used when averaging non-Federal average manufacturer price ("non-FAMP") across 11-digit National Drug Codes (NDC-11s).
- Unmet Medical Need: In section 60.3.3.1, CMS has revised the definition of unmet medical need to further align with FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics."[1]
- Addition of Manufacturer and Patient-Focused Meetings: To facilitate communication with manufacturers, CMS has described in section 60.4 that a CMS-manufacturer meeting will be added to the overall MFP negotiation process that would occur in Fall 2023 after the October 2, 2023 manufacturer data submissions, so that the manufacturer has an opportunity to present the data elements submission and share new information on the section 1194(e)(2) factors, if applicable, with CMS. In addition, CMS will be holding patient-focused listening sessions in Fall 2023 after the October 2, 2023 deadline for patients and other interested parties to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs.
- Negotiation Process: CMS revised section 60.4.3 to clarify that CMS will respond in writing no later than 30 days after receipt of a manufacturer's counteroffer regardless of whether CMS accepts or rejects the counteroffer. CMS has clarified that, to effectuate any MFP agreed upon by CMS and the Primary Manufacturer, both CMS and the Primary Manufacturer must sign and execute an Addendum to the Agreement. CMS also clarified in section 60.4.4 of the revised guidance that if an agreement on an MFP is not reached by the statutory end of the negotiation period, the Primary Manufacturer will enter a period during which an excise tax potentially may be assessed. The Primary Manufacturer can end this period by agreeing to an MFP or sending a notice terminating all of its applicable agreements under the Medicare and Medicaid programs and establishing that none of the Primary Manufacturer's drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act.
- Publication of MFPs for Selected Drugs: CMS clarified in section 60.6 of the revised guidance that CMS will publish the following on the CMS website by September 1, 2024 for all initial price applicability year 2026 selected drugs where an MFP was agreed upon: the selected drug, the initial price applicability year, and the MFP pricing file (which would be updated annually to show the inflation-adjusted MFP for a selected drug). CMS will strive to publish the explanation of the MFP earlier than March 1, 2025, if feasible.
- Manufacturer Delay in Negotiation Process: CMS has clarified in section 60.8 of the revised guidance that, if a Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, CMS will continue to engage in the negotiation process, as described in section 60.4. If delays occur such that the MFP is established after the end of the

[1] FDA Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics, May 2014. See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics.

negotiation period, CMS will follow timelines consistent with this revised guidance and take the time to complete the negotiation process as described.

Section 70 – Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect: In accordance with the policy clarification in section 30, CMS clarified that, in addition to monitoring PDE data for a selected drug, CMS will use AMP data reported by manufacturers to determine whether bona fide marketing is occurring when the agency undertakes the process of deselecting a selected drug and monitoring for the continued bona fide marketing of a generic drug or biosimilar. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of the generic drug or biosimilar biological product is engaging in bona fide marketing of that drug or product.

In addition, the revised guidance clarifies that status as a selected drug is unaffected by whether the Primary Manufacturer effectuates or terminates the Agreement to participate in the Negotiation Program or divests of the selected drug.

Section 80 – MFP-Eligible Individuals: CMS clarified in section 80 of this revised guidance that for initial price applicability year 2026, an MFP for a selected drug must be provided to a Medicare beneficiary who uses their Part D plan (including a Medicare Advantage Prescription Drug (MA-PD) plan under Medicare Part C or an Employer Group Waiver Plan) if Part D coverage is provided under such plan for such selected drug. The MFP is not required to be made available to a Medicare beneficiary who uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash. For initial price applicability year 2026, CMS does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to MFP eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan.

Section 90 – Manufacturer Compliance and Oversight: CMS made revisions to note that, while the statute clearly requires that the manufacturers of selected drugs are responsible for providing access of the MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers, CMS intends to engage with an MTF to facilitate the exchange of data between supply chain entities to verify eligibility of MFP-eligible individuals such that the MFP can be effectively passed through by the manufacturer to pharmacies, mail order services, and other dispensers. CMS also intends to explore options to facilitate retrospective payment exchange between interested parties to help effectuate access to the MFP.

Consistent with the changes and clarifications noted in sections 30 and 70 of this summary, CMS has also reaffirmed in section 90.4 of this revised guidance that it intends to monitor whether the manufacturer of a generic drug or biosimilar for the selected drug is engaging in “bona fide marketing” of the product by reviewing both PDE data and AMP data. CMS has also clarified that use of these data is not exhaustive, and all data and other information will be reviewed in totality in monitoring if manufacturers of these applicable generic drugs and biosimilars continue to engage in bona fide marketing.

Section 100 – Civil Monetary Penalties (CMPs): In the revised guidance, CMS has provided additional details on the CMP Notification that will be sent to the Primary Manufacturer, an opportunity for corrective action in applicable circumstances, additional details on CMP calculations, and information regarding the payment and appeals processes. CMS will provide an opportunity for corrective action prior to imposing CMPs in some circumstances, providing, for example, a Notice of Potential Noncompliance that includes an opportunity for the Primary Manufacturer to correct or mitigate noncompliance in applicable situations. CMS also revised the guidance to adopt a definition for "knowingly" that is consistent with language used by the Office of the Inspector General in administration of CMPs at 42 C.F.R. § 1003.110 such that "knowingly" means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required. CMS has also removed the "knowingly" requirement as related to the submission of false information under the Manufacturer Agreement.

Section 110 – Part D Formulary Inclusion of Selected Drugs: The revised guidance has clarified that the statute requires Part D plans to include on their formularies all dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect and has established the agency's expectations for how this requirement will be met for initial price applicability year 2026.

Section 120 – Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs: In the revised guidance, CMS has reaffirmed that selected drugs will also be subject to the Part D drug inflation rebate, but clarified that the MFP for a selected drug is not included in the AMP for the selected drug and thus will not affect the Part D inflation rebate calculation (see section 1927(k)(1)(B)(i)(VI)).

Appendix C – Definitions for Purposes of Collecting Manufacturer-Specific Data: After consideration of the comments on this guidance and the Negotiation Data Elements Information Collection Request (ICR) (CMS-10847 / OMB 0938-NEW), CMS has revised certain definitions in Appendix C. For example, CMS has revised the definition of non-FAMP in Appendix C to clarify that any restatements of the non-FAMP made in any applicable manufacturer non-FAMP submissions to the Department of Veterans Affairs must be reflected in the non-FAMP submitted to CMS as part of the section 1194(e)(1) data submission. CMS has consolidated several research and development (R&D) cost categories in Appendix C and has revised the R&D-related definitions by, for example, requiring reporting of acquisition costs as part of R&D rather than market data and revenue and sales volume data. CMS has also revised Appendix C to clarify that CMS will consider both a Primary Manufacturer's global and U.S. revenue when determining whether to adjust the preliminary price based on manufacturer-submitted data. In addition, CMS has revised the definition related to patents and exclusivities to provide clarification about the types of patents and patent applications that CMS considers to be "related to" the selected drug.

CMS removed certain definitions in Appendix C that are no longer needed due to deletions and revisions to information requested in the 30-day public notice for comment on the Negotiation Data Elements Information Collection Request, including 340B ceiling price, 340B prime vendor program price, manufacturer average net unit price to Part D plans, and quarterly total U.S. unit

volume. CMS revised the definition of unmet medical need and clarified when CMS will consider caregiver perspectives and outcomes such as changes to productivity, independence, and quality of life.

CMS directs interested parties to the 30-day public notice for comment on the Negotiation Data Elements ICR for revisions to ICR instructions and questions that are out of scope for this revised guidance.

C. Summary of Public Comments on the Initial Medicare Drug Price Negotiation Program Memorandum and CMS' Responses

CMS Statutory Authority to Issue Program Instruction and to Issue Section 30 of the Initial Memorandum as Final

Comment: Many commenters stated that CMS should use notice-and-comment rulemaking procedures to implement sections of the IRA. Specifically, a few commenters suggested that by issuing policy through program instruction, CMS violated the Administrative Procedure Act (APA) and the Medicare statute, which require use of notice procedures in certain circumstances and 60 days for comment. Relatedly, a few commenters stated that CMS violated the Due Process Clause of the U.S. Constitution by releasing section 30 of the initial memorandum as final without soliciting comments. Commenters asserted that in relying on the strict statutory deadlines for implementing the Negotiation Program as the rationale for issuing section 30 of the initial memorandum as final, CMS has not shown "good cause" to issue section 30 as final. In addition, a couple of commenters indicated that by issuing section 30 as final, CMS exceeded the scope of what Congress permitted in statute and engaged in *ultra vires* conduct.[2] Some commenters stated that it was improper for CMS to establish substantive obligations without providing notice and opportunity for comment, with one of these commenters further stating that such obligations are invalid and unenforceable because the guidance did not go through rulemaking procedures. A couple of commenters also wrote that the fact that CMS published the initial memorandum seven months after the IRA was enacted does not exempt it from providing opportunities for comment. Several commenters specifically requested that CMS use notice-and-comment rulemaking to codify the negotiation process for initial price applicability years 2027 and beyond. Other commenters recommended that CMS finalize the guidance well in advance of the selected drug publication date for initial price applicability year 2026 to provide interested parties with adequate time to review this revised guidance and conform their actions accordingly.

Response: Sections 11001(c) and 11002(c) of the IRA state that CMS "shall implement" the Negotiation Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." Thus, the initial memorandum is not subject to the notice-and-comment requirements of the APA or the Medicare statute. The terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. The statutory directive in sections 11001(c) and 11002(c) thus specifies that CMS shall follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under the APA or the

[2] *Ultra vires* means "beyond the powers," and is used to describe actions taken by governmental bodies that exceed the scope of power given to them by law.

Medicare statute. Congress underscored this directive by placing the Negotiation Program in the newly-enacted Part E of Title XI of the Social Security Act.

Even if the notice-and-comment procedures of the APA and the Medicare statute were applicable, the use of those procedures would be impracticable, unnecessary, and contrary to the public interest, and CMS thus had good cause to depart from those procedures. CMS solicited public comment on many key aspects of the initial memorandum, and also concluded, as stated in the initial memorandum, that in light of the complexity of the actions that must be undertaken in advance of the statutorily-mandated publication of the selected drug list by September 1, 2023, there was good cause to issue parts of the initial memorandum as final, including section 30, without soliciting public comment and without a delayed effective date. CMS reiterates this good-cause justification in this final guidance. CMS also has good cause to issue this revised guidance as final in advance of the statutory September 1, 2023, publication date of the selected drug list for initial price applicability year 2026. CMS agrees with the commenters who encouraged CMS to finalize the guidance well in advance of September 1, 2023 in order to allow interested parties advanced notice of the final policies for the Negotiation Program for initial price applicability year 2026. In particular, manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture will be included on the selected drug list for initial price applicability year 2026. For example, manufacturers may need to engage in internal discussions regarding whether the manufacturers would choose to participate in the Negotiation Program if their drug is included on the selected drug list published on September 1, 2023, review the template Medicare Drug Price Negotiation Program Agreement and guidance to understand Negotiation Program requirements for participating manufacturers in advance of the statutory deadline of October 1, 2023, for entering agreements, and gather information for potential submission to CMS by the statutory deadline of October 2, 2023. In addition, for the reasons explained below, the deadline for a biosimilar manufacturer to submit a delay request under section 1192(f) of the Act was May 22, 2023. CMS could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far in advance of these deadlines to allow them adequate time to complete their preparations for potential participation in the Negotiation Program.

Although section 30 was issued as final in the initial memorandum due to these timing constraints, CMS received many comments on section 30. In this guidance, CMS summarizes and responds to those comments, and CMS revised section 30 to help clarify, as needed, the policies it will follow to implement the selection of drugs for initial price applicability year 2026. CMS will continue to consider these comments as it develops guidance and rulemaking for future years of the Negotiation Program.

CMS also disagrees that the use of program guidance to implement the Negotiation Program for initial price applicability year 2026 or the issuance of section 30 as final violates the Due Process Clause of the U.S. Constitution. To the contrary, the reason CMS has undertaken efforts to finalize this guidance well before September 1, 2023, is to ensure that interested parties have advance notice about the procedures CMS will use to implement the Negotiation Program in accordance with the statute. The statute expressly directs CMS to use program guidance rather than notice-and-comment rulemaking to implement the Negotiation Program for 2026, 2027, and 2028, and, even so, through the publication of the initial memorandum, CMS ensured that

interested parties were given notice of and an opportunity to comment on many key aspects of the procedures CMS intends to follow in advance of any selection or negotiation for initial price applicability year 2026. And as explained, although CMS did not solicit comment on section 30, it received many comments on that section and revised to clarify the section in light of those comments.

Further, since enactment of the IRA in August 2022 CMS has engaged with interested parties through various platforms. On January 11, 2023, CMS issued a memorandum outlining how CMS will approach implementation of the Negotiation Program for initial price applicability year 2026, including engagement with the public; program guidance; information collection requests; and a timeline outlining key dates.[3] CMS considered the feedback it received through this engagement in the development of the initial memorandum for the Negotiation Program. Following the issuance of the initial memorandum in March 2023, CMS continues to engage with interested parties, with the intention to engage interested parties throughout implementation of the Negotiation Program.

Between September 2022 and March 2023, CMS accepted 104 meetings with interested parties representing the views of consumer and patient organizations, health care providers, health plans, PBMs, pharmaceutical and biotechnology manufacturers, pharmacies, researchers and academic experts, and wholesalers. In these meetings, CMS leadership and staff received feedback on implementation of the Negotiation Program ranging from policy concerns, questions requiring clarification, and recommendations on policy or operations. CMS also received 129 written materials totaling more than 1,100 pages submitted by pharmaceutical and biotechnology manufacturers and their trade associations, researchers and academic experts, consumer and patient organizations, and health plans and their trade associations, among other interested parties, before publishing the initial memorandum. Based on CMS' tracking of meeting agendas and materials provided, interested parties commonly provided feedback on key Negotiation Program topics including how to identify qualifying single source drugs for negotiation, how to apply the Orphan Drug Exclusion, how to operationalize requests by a biosimilar sponsor to delay selection and negotiation of a biological product that is a reference product for biosimilar market entry, and how to effectuate the MFP. Additionally, CMS leadership participated in 22 speaking engagements on IRA implementation hosted by interested parties. In addition to meetings with interested parties on specific issues of importance to the individual company or organization, CMS has held monthly one-hour calls open to all pharmaceutical and biotechnology manufacturers since December 2022. During these monthly calls, CMS staff provide an overview of recent IRA activities and take questions from manufacturer participants. In addition, in Fall of 2022, CMS established an IRA webpage for all program policies and updates and created an IRA mailbox (IRARebateandNegotiation@cms.hhs.gov) to receive queries from the public related to implementation of the Part B and Part D Inflation Rebate Program and the Negotiation Program. For example, CMS has received queries through the IRA mailbox from interested parties on how to ensure beneficiaries have access to the MFP through their Part D plan.

[3] CMS memorandum *Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026.* Accessible at https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf.

Through external meetings with interested parties, monthly IRA calls with pharmaceutical and biotechnology manufacturers, and the IRA mailbox, interested parties have had multiple touchpoints with CMS. Therefore, CMS disagrees that it has not provided opportunity for interested parties to engage with CMS on policies that may impact their business operations and patients. CMS remains committed to ongoing engagement efforts with interested parties and plans to meet with the Primary Manufacturer of each selected drug as well as hosting patient-focused listening sessions on the selected drugs in Fall 2023, as described in section 60.4 of this revised guidance.

Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2026 (Section 30.1)

Comment: CMS received many comments on its reading of the statute to aggregate all dosage forms and strengths of a drug with the same active moiety and the same holder of the NDA or of a biological product with the same active ingredient and the same holder of the BLA, for the purposes of identifying potential qualifying single source drugs. Some commenters stated that this approach is consistent with the clear statutory instruction to aggregate across dosage forms and strengths. A couple of commenters stated that this policy is critical to prevent gaming. In their view, this reading of the statute will prevent pharmaceutical manufacturers from engaging in "product hopping," attempting to shift use of their products away from those with an MFP to those without an MFP, based solely on modest or minor modifications, a practice which increases revenue for pharmaceutical companies. Other commenters asserted that this approach is not supported by the statute and that the statute defines a qualifying single source drug in reference to a distinct NDA or BLA.

Response: Section 1192(d)(3)(B) of the Act directs CMS to "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug" for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures "to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug." The aggregation rules under sections 1192(d)(3)(B) and 1196(a)(2) are clear, and are designed to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries as intended by the law. Because different dosage forms and strengths, as well as different formulations, of an active moiety / active ingredient can be approved or licensed under multiple NDAs or BLAs, the suggestion from commenters to define a qualifying single source drug in reference to a distinct NDA or BLA is inconsistent with sections 1192(d)(3)(B) and 1196(a)(2) of the Act. Contrary to the views of some commenters, section 1192(d)(3)(B) refers to the aggregation of data "across dosage forms and strengths of the drug, including new formulations of the drug," thereby necessarily establishing that the statutory negotiation procedures apply more broadly than to a distinct NDA or BLA. Unlike the views offered by some commenters, CMS' understanding of the statutory language gives full effect to all relevant provisions of the statute, including sections 1192(e), 1192(d)(3)(B), and 1196(a)(2) of the Act; CMS is applying an interpretation of the statute that follows the statutory criteria for the identification of a qualifying single source drug under section 1192(e) of the Act and,

consistent with sections 1192(d)(3)(B) and 1196(a)(2) of the Act, gives effect to the statutory policy that a drug that may be selected for negotiation includes multiple dosage forms and strengths and formulations of that drug.

CMS agrees with commenters that complying with the statutory requirement to identify a qualifying single source drug using data that is aggregated across different dosage forms and strengths, as described in the initial memorandum, will decrease incentives for pharmaceutical manufacturers to engage in "product hopping." This statutory requirement ensures that products by the same sponsor with the same active moiety / active ingredient are subject to the same processes under the Negotiation Program, and that a manufacturer is therefore limited in its ability to shift use of its products away from those with an MFP to those without an MFP, based on modest or minor modifications. Reducing "product hopping" is consistent with the purpose of the statute, which is to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries. For the above reasons, in this revised guidance, CMS maintains the approach described in the initial memorandum for identifying potential qualifying single source drugs.

Comment: Some commenters raised questions about how CMS will treat products that have different formulations or routes of administration within the same qualifying single source drug, given the policy to define a qualifying single source drug based on active moiety or active ingredient. Some commenters expressed concerns that aggregation will limit pharmaceutical innovation, including innovation for rare diseases and conditions, and commenters urged CMS to consider the patient perspective on whether new formulations demonstrate an improvement to patient care. In contrast, one commenter was concerned that aggregating products with different indications and/or routes of administration into the same qualifying single source drug could be problematic because one product with different indications and/or routes of administration from the other products within a potential qualifying single source drug could have a generic or biosimilar competitor that would disqualify all products from the Negotiation Program.

Response: CMS thanks these commenters for their input. CMS is committed to recognizing the clinical benefit of products, including products with different formulations or routes of administration from other products that are aggregated as part of the same qualifying single source drug, and directs readers to section 60.3.3 of this revised guidance, which details CMS' approach to adjusting the starting point for an initial offer based on clinical benefit.

CMS appreciates the concern raised that a generic or biosimilar competitor for one product within a potential qualifying single source drug will disqualify all products within that potential qualifying single source drug from the Negotiation Program. However, as explained above, the statute directs CMS to aggregate across dosage forms and strengths of the drug, and CMS must apply that requirement faithfully not only for purposes of identifying the qualifying single source drug, but also for purposes of disqualifying products with generic or biosimilar competition that satisfies the relevant statutory criteria.

CMS is committed to ensuring that the statutory criteria are satisfied for any such disqualification, including the requirement that a generic or biosimilar be "marketed." This is particularly important given that a drug or biological product will not be considered a qualifying

single source drug for initial price applicability year 2026 if such competition is determined to exist at the time of drug selection; if such determination occurs after drug selection, it will cause a selected drug (1) to be no longer subject to the negotiation process or (2) to cease to be a selected drug, depending on the timing of such determination. CMS directs readers to section 90.4 of this revised guidance, which details how CMS will monitor whether a generic drug or biosimilar competitor is engaging in bona fide marketing such that a potential qualifying single source drug is disqualified from participation in the Negotiation Program.

Comment: Many commenters asserted that the distinct time periods for when a drug versus biological product will be eligible for negotiation are arbitrary and that CMS should implement the Negotiation Program so that, for any drug or biological product to qualify as a qualifying single source drug, at least 11 years must have elapsed since the drug or biological product was approved or licensed, respectively.

Response: Section 1192(e)(1)(A)(ii) of the Act states that for a drug product to be considered a qualifying single source drug, at least 7 years must have elapsed since the drug product was approved by the FDA.[4] Section 1192(e)(1)(B)(ii) of the Act states that for a biological product to be considered a qualifying single source drug, at least 11 years must have elapsed since the biological product was licensed by the FDA.[5] CMS is implementing the program in accordance with these statutory requirements.

Comment: A couple of commenters expressed support for CMS' reading of the statute in the initial memorandum on fixed combination drugs with two or more active moieties / active ingredients, which treats the distinct combination of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs. One commenter raised a concern that this reading, while sensible in some cases, creates a gaming opportunity for manufacturers to seek approval of fixed combination drugs with one active moiety / active ingredient in common and market them in a way that could influence volume for each fixed combination drug in an effort to avoid selection. For example, a sponsor might market a fixed combination drug that contains active moiety / active ingredient X and Y and a fixed combination drug that contains active moiety / active ingredient X and Z. The commenter encouraged CMS to aggregate sales for fixed combination drugs with other dosage forms containing the newest active moiety / active ingredient if the products are made by the same manufacturer.

Response: CMS appreciates commenters' support for its understanding of the statutory language and acknowledges the concern outlined by one commenter. CMS believes that a fixed combination drug is distinct in its composition from the individual active moieties / active ingredients and in this revised guidance maintains its approach on fixed combination drugs,

[4] For drug products, to determine the date of approval for a potential qualifying single source drug with more than one FDA application number, section 30.1 of this revised guidance specifies that CMS will use the earliest date of approval of the initial FDA application number assigned to an NDA for the active moiety for which the manufacturer is the holder of the NDA.

[5] For biological products, to determine the date of approval for a potential qualifying single source drug with more than one FDA application number, section 30.1 of this revised guidance specifies that CMS will use the earliest date of licensure of the initial FDA application number assigned to a BLA for the active ingredient for which the manufacturer is the holder of the BLA.

which treats the distinct combination of active moieties / active ingredients as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs.

Orphan Drug Exclusion from Qualifying Single Source Drugs (Section 30.1.1)

Comment: Many commenters asked CMS to clarify that the 7- or 11-year periods prior to eligibility as a qualifying single source drug would begin on the date the Orphan Drug Exclusion ceases to apply to a drug or biological product. That is, a drug or biological product could not become a qualifying single source drug until 7 or 11 years had passed between the date on which the drug or biological product, respectively, loses eligibility for the Orphan Drug Exclusion and the selected drug publication date.

Response: CMS does not have the statutory authority to change the starting date from which qualifying single source drug status is determined. Sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act require CMS to use the date of the approval or licensure of the drug or biological product to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Act. CMS has added language to section 30.1.1 of this revised guidance to clarify the timing that CMS will use to identify qualifying single source drugs.

Comment: Many commenters asserted that drugs or biological products with multiple orphan designations (for multiple rare diseases or conditions) that are approved only for indications within the scope of a single rare disease or condition should qualify for the Orphan Drug Exclusion. A few commenters remarked that designating a drug under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for a rare disease is done very early in the drug development process and is important to unlocking Orphan Drug Act incentives. These commenters expressed concern that the current Orphan Drug Exclusion policy in the Negotiation Program will stymie innovation for drugs or biological products and discourage sponsors from seeking designations for more than one rare disease or condition.

Response: CMS thanks these commenters for their feedback. Section 1192(e)(3)(A) of the Act describes a drug that qualifies for the Orphan Drug Exclusion as a "drug that is designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and for which the only approved indication (or indications) is for such disease or condition." CMS therefore does not have the statutory authority to exclude a drug under the Orphan Drug Exclusion that has designations for multiple rare diseases or conditions, even if the drug has been approved only for indication(s) within a single rare disease or condition. CMS has added a clarification about designations for multiple rare diseases or conditions to section 30.1.1 of this revised guidance, which addresses how CMS will implement this exclusion.

Comment: A couple of commenters urged CMS to interpret the term "rare disease or condition" with sufficient breadth to capture designations and approved indications for different mutations or subtypes of one disease. Commenters noted that this interpretation would allow a drug or biological product to seek designations and approvals for sub-conditions within the same rare

disease or condition and remain eligible for the Orphan Drug Exclusion and would preserve incentives for drug development across sub-conditions.

Response: CMS will follow the statutory directive in section 1192(e)(3)(A) of the Act to consider orphan designations and approvals within the scope of the same rare disease or condition. As clarified in section 30.1.1 of this revised guidance, CMS will consult with the FDA as needed to determine whether a drug is designated under section 526 of the FD&C Act for, or has approved indications for, one or more rare diseases or conditions, as part of determining whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the Orphan Drug Exclusion.

Comment: Commenters offered contrasting perspectives on whether CMS should consider orphan designations that have been withdrawn when evaluating a drug or biological product for the Orphan Drug Exclusion. Some commenters asserted that CMS should not consider withdrawn designations. In contrast, one commenter recommended that CMS should consider withdrawn designations because a manufacturer could withdraw a designation that is not yet FDA-approved so that a drug or biological product could qualify for the Orphan Drug Exclusion.

Response: CMS appreciates this feedback. CMS understands that a drug or biological product may be designated for a rare disease or condition early in the drug development process, and that designation might not always result in FDA-approved indications that fall within the scope of that designation, and that a manufacturer may choose to withdraw the designation. Similarly, there may be situations where, for example, a manufacturer decides to request that FDA withdraw approval of an indication. In accordance with section 1192(e)(3)(A) of the Act, only designations and approvals active at the time of identifying qualifying single source drugs will be considered for purposes of determining a drug's eligibility for the Orphan Drug Exclusion to best reflect the status of the drug at the time it is evaluated for qualifying single source drug eligibility. As such, CMS has clarified in section 30.1.1 of this revised guidance that it will not consider withdrawn orphan designations or withdrawn approvals when evaluating a drug for the Orphan Drug Exclusion.

Comment: A few commenters raised questions as to whether a potential qualifying single source drug will qualify for the Orphan Drug Exclusion if some but not all dosage forms and strengths of that potential qualifying single source drug meet the Orphan Drug Exclusion criteria. One commenter requested that, when a drug or biological product loses eligibility for the Orphan Drug Exclusion, CMS carve out the original approval(s) that qualified for the Orphan Drug Exclusion from the resulting qualifying single source drug. Another commenter requested that potential qualifying single source drugs that qualify for the Orphan Drug Exclusion must qualify across all dosage forms and strengths. An additional commenter asked whether a fixed combination drug will qualify for the exclusion if only one of the two active moieties / active ingredients qualifies for the Orphan Drug Exclusion.

Response: The initial memorandum states that, in order to qualify for the Orphan Drug Exclusion, "all dosage forms and strengths and different formulations of the qualifying single source drug described in section 30.1 of this memorandum must meet the criteria for exclusion." In this revised guidance, CMS maintains this requirement. Because section 1192(e)(3)(A) of the

Act is an exclusion from the definition of qualifying single source drug under section 1192(e)(1) of the Act, CMS must consider whether the drug, including all products that constitute the potential qualifying single source drug, meets the statutory criteria for the Orphan Drug Exclusion.

Comment: A few commenters expressed concern that the FDA Orphan Drug Product designation database and the FDA approvals database will not allow CMS to identify whether an indication falls within an orphan designation. To alleviate this concern, commenters recommended that CMS consult with FDA and consider written communications between FDA and the manufacturer during the review and approval process. Commenters also suggested that CMS establish a pathway for manufacturers and other interested parties to demonstrate that an indication falls within an orphan drug designation.

Response: CMS appreciates these comments. CMS believes that consulting the FDA Orphan Drug Product designation database and approvals on the FDA website, in addition to consultation with FDA as needed, will allow CMS to successfully implement the Orphan Drug Exclusion. CMS will monitor this approach to ensure that it accurately operationalizes the Orphan Drug Exclusion.

Comment: A few commenters requested that CMS support the development of diagnosis codes for rare diseases and disorders; support early dialogue between payers and rare disease manufacturers; and create new payment and service delivery models with the Center for Medicare and Medicaid Innovation (CMMI) that bolster innovation in the treatment of rare diseases or conditions.

Response: CMS noted in the initial memorandum that CMS is considering whether there are additional actions that CMS might take in its implementation of the Negotiation Program to support orphan drug development, and CMS directs readers to the discussion in section 60.3.3 of how it will consider unmet medical need and the impact of a selected drug on specific populations when developing the initial offer. CMS notes, however, that these specific requests related to CMMI, diagnosis code development, and other payers' interactions with manufacturers are outside the scope of this revised guidance.

Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs (Section 30.1.2)

Comment: A few commenters provided feedback on CMS' description of how it will calculate the Low-Spend Medicare Drug Exclusion. One commenter supported the approach that CMS detailed in the initial memorandum. Another commenter recommended that CMS include rebates in the calculation of Total Expenditures under Part B and Part D for purposes of the Low-Spend Medicare Drug Exclusion. One commenter recommended that CMS exclude beneficiary cost sharing under Part B and net out Direct and Indirect Remuneration (DIR) under Part D when calculating total Part B and Part D expenditures for purposes of this exclusion.

Response: For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) of the Act as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3) of the Act). The term "gross covered prescription

drug costs" is also defined in the Part D regulations at 42 C.F.R. § 423.308. In the initial memorandum, CMS indicated that it had proposed to update this regulatory definition of gross covered prescription drug costs to eliminate any potential ambiguity in the regulation text and help to ensure there is a consistent understanding of the term for purposes of both the Part D program and the IRA. Since the initial memorandum was issued, CMS has issued a final rule adopting the proposed revisions to 42 C.F.R. § 423.308 (see Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Final Rule (0938-AU96), 88 Fed. Reg. 22,120, 22,259 (Apr. 12, 2023)).[6] CMS has updated this revised guidance to reflect the issuance of the final rule.

Using PDE data combined with Part B claims data, inclusive of beneficiary cost sharing, to calculate combined Total Expenditures under Part D and Part B will allow CMS to implement the Low-Spend Medicare Drug Exclusion in a manner that aligns with the statute and regulatory policy. CMS will use Part B claims data that are inclusive of beneficiary cost sharing to determine Part B Total Expenditures to maintain consistency with the approach to determining "gross covered prescription drug costs" under Part D, which are defined in the statute and regulations as inclusive of Part D beneficiary cost sharing. CMS has clarified in section 30.1.2 of this revised guidance that, in accordance with section 1191(c)(5) of the Act, expenditures for a drug or biological product that are bundled or packaged into the payment for another service are excluded from the calculation of total allowed charges under Part B for purposes of determining Total Expenditures under Part B.

Comment: One commenter asked CMS to clarify that the 30-day additional period from June 1, 2023 to June 30, 2023 for Part D plan sponsors and Part B providers and suppliers to submit PDE and Part B claims data is a grace period.

Response: As described in section 30.1.2 of this revised guidance, the 30-day period from June 1, 2023 to June 30, 2023 provides time for data to be submitted. In identifying low-spend Medicare drugs for initial price applicability year 2026, CMS will only consider PDE data and Part B claims with dates of service that occur during the 12-month period beginning June 1, 2022, and ending May 31, 2023.

Plasma-Derived Product Exclusion from Qualifying Single Source Drugs (Section 30.1.3)

Comment: Some commenters asked CMS to provide further clarification on which products will be considered plasma-derived for the purpose of the Plasma-Derived Product Exclusion. A couple of commenters asserted that cellular or gene therapies should not be subject to the exclusion. A couple of commenters requested a more holistic approach to identifying plasma-derived products, such as through consultation with FDA and other interested parties.

Response: CMS continues to believe that referring to product information available on the FDA Approved Blood Products website[7] and the FDA Online Label Repository[8] is the best way to

[6] Accessible at: https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.
[7] See: https://www fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[8] See: https://labels.fda.gov/.

identify plasma-derived products for the purpose of implementing the Plasma-Derived Product Exclusion in a consistent manner. CMS agrees that there may be specific products where additional insights from FDA would be beneficial, and as noted in section 30.1.3, CMS will also consult with FDA as needed to implement this exclusion.

CMS confirms that cellular and gene therapies are not categorically ineligible for the Plasma-Derived Product Exclusion described in section 1192(e)(3)(C) of the Act, which applies the exclusion to biological products derived from human whole blood or plasma. As described by FDA, cellular therapy products include cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications. As further described by FDA, human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use.[9] Cellular and gene therapies will be assessed using the same standards as other biological products to determine whether they qualify for the Plasma-Derived Product Exclusion.

Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2026 (Section 30.2)

Comment: One commenter asked CMS to clarify whether rebates will be incorporated into the calculations used to rank the 50 negotiation-eligible drugs.

Response: In identifying and ranking the negotiation-eligible drugs for initial price applicability year 2026, CMS will use Total Expenditures under Part D, which are defined at section 1191(c)(5) of the Act as "total gross covered prescription drug costs," as defined in section 1860D-15(b)(3). Section 1860D–15(b)(3) of the Act defines "gross covered prescription drug costs" in relevant part as "the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible." The term is also defined in the Part D regulations at 42 C.F.R. § 423.308. As discussed in the Contract Year 2024 Final Rule (see 88 Fed. Reg. 22,120, 22,259 (Apr. 12, 2023)), costs directly related to the dispensing of covered Part D drugs are most logically calculated as the accumulated total of the negotiated prices that are used for purposes of determining payment to the pharmacy or other dispensing entity for covered Part D drugs. Consistent with this policy, CMS will calculate Total Expenditures under Part D for purposes of the Negotiation Program using PDE data and will not consider any rebates or other price concessions not reflected in the negotiated price of the drug on the PDE to identify and rank negotiation-eligible drugs.

[9] See: https://www fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products.

Exception for Small Biotech Drugs (Section 30.2.1)[10, 11]

Comment: A couple of commenters requested that CMS create a dispute resolution process so that a manufacturer that disagrees with CMS' determination of its eligibility for the Small Biotech Exception can dispute this determination. One commenter requested that CMS allow small biotech companies to provide additional data after the deadline to support their application for the exception before CMS makes a final determination.

Response: CMS thanks these commenters for their recommendations. CMS requests all information necessary to determine eligibility for the Small Biotech Exception in the Small Biotech Exception ICR Form. Additionally, because of the ambitious statutory deadlines for the Negotiation Program for initial price applicability year 2026, CMS will not accept incomplete or late requests for the Small Biotech Exception for initial price applicability year 2026, including additional data submitted by companies to support their application after the deadline, but before CMS makes a final determination. CMS also declines to create a dispute resolution process for the Small Biotech Exception.

Comment: A couple of commenters requested further detail on the Small Biotech Exception for initial price applicability years 2027 and 2028. Commenters recommended that CMS introduce a streamlined application for manufacturers that had previously received the exception, wherein such manufacturers would only have to attest that they have not been acquired by another entity in order to receive the exception again. One commenter requested clarity on whether manufacturers only have one chance to apply for the Small Biotech Exception or if a manufacturer may submit each year.

Response: This revised guidance establishes the policies CMS will use to implement the Negotiation Program for initial price applicability year 2026. A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years. CMS will share the submission process for the Small Biotech Exception for initial price applicability years 2027 and 2028 in future guidance and appreciates the feedback received from commenters.

Comment: One commenter asserted that, for the purpose of identifying drugs that qualify for the Small Biotech Exception for initial price applicability year 2026, CMS must consider whether

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[10] On January 24, 2023, CMS released the Small Biotech Exception ICR (CMS-10844 / OMB 0938-1443) to detail the specific data that CMS is requesting for purposes of implementing this exception. The comment period for the 60-day notice closed on March 27, 2023, and the comment period for the 30-day notice closed on May 24, 2023. Section 30.2.1 of this revised guidance reflects revisions that CMS made in response to feedback from interested parties on the Small Biotech ICR and section 30.2.1 of the initial memorandum. Here, CMS responds to comments on the discussion of the Small Biotech Exception in the initial memorandum that raised inquiries or recommendations not already addressed by revisions to the Small Biotech ICR. To view the Small Biotech ICR Form, a summary of changes made to the Small Biotech ICR in response to comments received during the 60-day and 30-day notice periods, as well as comments received on the Small Biotech ICR and CMS' responses to those comments, please see https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016.

[11] On June 2, 2023, CMS released the Small Biotech Exception functionality in CMS HPMS. To request the Small Biotech Exception for a qualifying single source drug for initial price applicability year 2026, manufacturers must submit a Small Biotech Exception request via HPMS by 11:59 p m. PDT on July 3, 2023.

Total Expenditures for a qualifying single source drug meet the expenditure requirements under either Part B or Part D. If the qualifying single source drug meets the requirements with respect to either Part B or Part D Total Expenditures, then that qualifying single source drug would qualify for the Small Biotech Exception.

Response: CMS appreciates this recommendation but, for initial price applicability year 2026, sections 1191(a) and 1192(d) of the Act require CMS to evaluate whether a qualifying single source drug meets the criteria to be considered a negotiation-eligible drug, including with respect to the Small Biotech Exception, based on Total Expenditures under Part D only.

Comment: One commenter requested that CMS make the Small Biotech Exception permanent rather than exclude small biotech drug products for only the first three years of the Negotiation Program.

Response: The Small Biotech Exception, as required by section 1192(d)(2)(A) of the Act, applies only with respect to initial price applicability years 2026, 2027, and 2028. CMS does not have the authority to make the Small Biotech Exception permanent.

Although the Small Biotech Exception is limited to initial price applicability years 2026, 2027, and 2028, CMS notes that the temporary floor for small biotech drugs described in section 1194(d) applies to qualifying single source drugs described in section 1192(d)(2) with respect to initial price applicability years 2029 and 2030.

Comment: One commenter requested that CMS clarify which 2021 Total Expenditure data it will use to determine eligibility for the Small Biotech Exception.

Response: As described in section 30.2.1 of this revised guidance, CMS will use PDE data for dates of service during the 12-month period beginning January 1, 2021 and ending December 31, 2021 to determine eligibility for the Small Biotech Exception.

Selection of Drugs for Negotiation for Initial Price Applicability Year 2026 (Section 30.3)

Comment: A few commenters requested greater transparency into the process of selecting drugs for negotiation. A couple of commenters requested that CMS notify the manufacturer of a drug that will be selected for negotiation at least 30 days in advance of the selected drug list publication date. One commenter asked that CMS publish the calculations used to determine the list of selected drugs and establish a process for manufacturers to identify concerns in advance of the selected drug publication date. A couple of commenters suggested that CMS establish a pathway for interested parties to provide input into which negotiation-eligible drugs are included on the selected drug list.

Response: For initial price applicability year 2026, the statute requires that CMS publish the selected drug list no later than September 1, 2023. CMS believes that disclosing to manufacturers whether their drug is a selected drug before this date is operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by September 1, 2023 for

initial price applicability year 2026. For example, sections 1191(d)(3)(B) and 1192(d)(1)(A) of the Act require that CMS identify negotiation-eligible drugs for initial price applicability year 2026 using Total Expenditure data during the period beginning on June 1, 2022, and ending on May 31, 2023. As discussed in section 30 of this revised guidance, Total Expenditures under Part D will be calculated using PDE data for dates of service between June 1, 2022 and May 31, 2023. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service during this 12-month period that have been submitted to CMS by June 30, 2023. The complexity of the data analyses and quality checks that must then be performed on the data prior to September 1, 2023 forecloses the possibility of disclosing to manufacturers whether their drug is a selected drug prior to the statutory selected drug list publication date for initial price applicability year 2026.

Although CMS appreciates the request for a pathway for interested parties to provide input into the selected drug list for initial price applicability year 2026, section 1192(b)(1)(B) of the Act requires that CMS select the highest ranked drugs from the list of negotiation-eligible drugs using Total Expenditures under Part D. CMS is committed to engaging with interested parties throughout the implementation of the Negotiation Program. As detailed earlier in this guidance, CMS solicited input from interested parties throughout the development of the initial memorandum and this revised guidance. Further, CMS refers readers to sections 50.2 and 60.3.3 of this revised guidance, which detail CMS' approach to adjusting the starting point for the initial offer using evidence submitted by the public on therapeutic alternatives to the selected drug, in accordance with section 1194(e)(2) of the Act. CMS also refers readers to section 60.4 of this guidance, which describes how, in response to comments from interested parties, CMS is providing for additional engagement opportunities for interested parties—specifically, meetings with manufacturers and patient-focused listening sessions—after the October 2, 2023 deadline for submission of section 1194(e) data.

Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry) (Section 30.3.1)

Comment: One commenter expressed support for a stringent process for assuring that a Biosimilar Manufacturer and Reference Manufacturer cannot have entered into agreements that require or induce the Biosimilar Manufacturer to limit market share, as well as the process for assuring that there is a high likelihood that the Biosimilar will be marketed before September 1, 2025. The commenter urged CMS to apply similar levels of scrutiny to all areas of implementation where proof of competition is required, including the definition of a qualifying single source drug.

Response: CMS appreciates this commenter's perspective. Section 1192(f)(2)(D)(iv) of the Act excludes certain Biosimilar Manufacturers from the Biosimilar Delay if CMS determines that the Biosimilar Manufacturer is the same as the Reference Manufacturer, or that the Biosimilar Manufacturer has entered into any agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or that restricts the quantity (either directly or indirectly) of the Biosimilar that may be sold in the United States over a specified period of time. As described in section 90.4 of this revised guidance, CMS plans to monitor whether the manufacturer of a generic or biosimilar competitor of a potential qualifying

single source drug or selected drug is engaging in bona fide marketing when identifying qualifying single source drugs and selected drugs.

Comment: One commenter expressed concern that a Reference Manufacturer will not have transparency into whether a Reference Drug will be a selected drug because the Reference Manufacturer will not know whether a Biosimilar Manufacturer has submitted an Initial Delay Request to delay the inclusion of that Reference Manufacturer's Reference Drug on the selected drug list. The commenter recommended that CMS publish a list of Biosimilar Manufacturers submitting an Initial Delay Request and make CMS' determinations known publicly.

Response: CMS thanks this commenter for raising this issue. The submission of an Initial Delay Request does not guarantee that a Reference Drug would be a selected drug absent the Initial Delay Request, nor does it guarantee that the Initial Delay Request will be granted even if the Reference Drug would be a selected drug absent the Biosimilar Delay. CMS, therefore, will not publish a list of Biosimilar Manufacturers submitting an Initial Delay Request or CMS' determinations. However, as described in section 30.3.1.4 of this revised guidance, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request of CMS' determination regarding such request on or after September 1, 2023, but not later than September 30, 2023. CMS will also notify each Reference Manufacturer named in a successful Initial Delay Request and will identify the Reference Drug that would have been a selected drug, absent the successful Initial Delay Request. In recognition that the public has an interest in understanding the impact of the Biosimilar Delay, CMS is clarifying in this revised guidance that it will publish the number of Reference Drugs that would have been selected drugs for initial price applicability year 2026, absent successful Initial Delay Requests, as part of publishing the selected drug list by September 1, 2023.

Comment: Some commenters asserted that the information required from a Biosimilar Manufacturer to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025 is too narrow. A couple of commenters contended that section 1192(f)(1)(B)(ii)(I)(aa) of the Act directs CMS to consider all documents that a Biosimilar Manufacturer believes support a high likelihood determination. One commenter stated that the Act does not specify that the scenarios described in sections 1192(f)(3)(A) and (B) are the only scenarios under which a high likelihood determination can be made. The commenter noted that other documentation should therefore suffice to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

Response: CMS thanks these commenters for their feedback related to the high likelihood determination. Section 30.3.1.2 of this revised guidance aligns with the statutory language, which requires CMS to identify whether a Biosimilar has a high likelihood of being licensed and marketed within two years after the publication of the selected drug list. CMS believes the information detailed in section 30.3.1.2 will allow CMS to implement the high likelihood provision of the Biosimilar Delay in a manner that benefits the Medicare program by minimizing the likelihood of CMS approving a delay request for a Biosimilar that is not highly likely to become licensed and marketed within two years after the publication of the selected drug list. Further, CMS believes this approach will support robust biosimilar competition.

Comment: One commenter stated that the metrics proposed to assess the operational readiness of a Biosimilar Manufacturer are generally sensible, but filings with the Securities and Exchange Commission (SEC) on future revenues are often subject to significant caveats about uncertainty and changing market conditions. The commenter recommended that CMS consider a more concrete indicator of operational readiness but did not provide any examples.

Response: CMS believes that section 30.3.1.2 of the guidance aligns with the statutory language and that SEC filings, despite any potential uncertainties, represent a meaningful source of information about a manufacturer's plans to manufacture and market a drug. CMS also notes that, in determining whether a Biosimilar Manufacturer will be operationally ready to market the Biosimilar before September 1, 2025, CMS will also consider supporting documentation provided to CMS as part of the Initial Delay Request, such as the copy of the manufacturing schedule submitted to FDA, which as CMS has clarified in section 30.3.1.2 of this revised guidance, must be consistent with public-facing statements and demonstrative of readiness to meet revenue expectations. Further, operational readiness is only one component of the high likelihood determination. To meet the high likelihood threshold, the Initial Delay Request must also demonstrate that an application for licensure under section 351(k) of the Public Health Service Act ("PHS Act") for the Biosimilar has been accepted for review or approved by FDA, and that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025.

Comment: One commenter explained that, upon review of a BLA, FDA may issue a Complete Response letter identifying the deficiencies that preclude approval. The applicant will generally work to address the deficiencies and resubmit the section 351(k) BLA, and FDA will generally act on a resubmitted section 351(k) BLA within six months of receipt. The commenter recommended that CMS make clear that a section 351(k) BLA in Complete Response status remains eligible for the Special Rule Delay.

Response: CMS thanks this commenter for the recommended clarification. CMS has clarified in section 30.3.1.2 of the guidance that CMS will consider a section 351(k) application for licensure that has been accepted for review and has received a Complete Response letter to meet the section 1192(f)(3)(A) requirement that a section 351(k) BLA for the biosimilar biological product has been accepted for review by FDA.

Comment: One commenter recommended that CMS collaborate with FDA to identify key milestones that would indicate a high likelihood that a Biosimilar will be licensed and marketed before September 1, 2025.

Response: Both the initial memorandum and revised guidance incorporate technical assistance from FDA along with other federal agencies. To demonstrate there is a high likelihood that a Biosimilar will be licensed and marketed before September 1, 2025, an Initial Delay Request must demonstrate that the Biosimilar meets the high likelihood threshold described in section 30.3.1.2 of the revised guidance. This threshold requires that, for Initial Delay Requests submitted with respect to initial price applicability year 2026, the Biosimilar's application for licensure must be approved or accepted for review by FDA no later than August 15, 2023, and that the Initial Delay Request demonstrate clear and convincing evidence that the Biosimilar will

be marketed before September 1, 2025. The clear and convincing evidence criteria will be satisfied if the Initial Delay Request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. CMS will continue to consult with FDA as needed on its policies for implementing the Biosimilar Delay.

Comment: One commenter stated that the purpose of the manufacturing schedule submitted to FDA during FDA's review of a section 351(k) BLA – and to CMS under section 1192(f)(1)(B)(ii)(III)(aa) of the Act – is to facilitate an FDA inspection of the establishment that is manufacturing the biological product to confirm the establishment is in operation and manufacturing the proposed product. This manufacturing schedule, therefore, does not reflect any post-approval manufacturing dates. The commenter advised CMS to omit the reference to "consistent with the public-facing statements and any revenue expectations" in the revised guidance.

Response: CMS thanks this commenter for offering their perspective on the uses of the manufacturing schedule submitted to FDA during FDA's review of a section 351(k) BLA. CMS has included a clarification in section 30.3.1.2 of this revised guidance that the manufacturing schedule must be consistent with the manufacturer's public-facing statements and demonstrate readiness to meet revenue expectations, in recognition that the schedule does not reflect post-approval manufacturing dates.

Comment: A few commenters remarked that ongoing patent litigation may be irrelevant to a Biosimilar launch. A Biosimilar Manufacturer can carve out indications with active patents from the Biosimilar's labeling, or a Biosimilar can launch at risk. The commenters asserted that active litigation should, therefore, not prevent manufacturers from meeting the high likelihood threshold.

Response: CMS has clarified that an Initial Delay Request for initial price applicability year 2026 only has to meet one of the following criteria to satisfy the patent-related component of the high likelihood determination: (1) there are no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer. For example, if a Biosimilar Manufacturer has carved out a patent-protected indication or method of use from the Biosimilar's labeling, then such patents would not be considered to be "applicable to the Biosimilar." CMS reiterates that the above criteria reflect how CMS will determine if the Initial Delay Request clearly demonstrates that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025.

Comment: A few commenters requested that CMS clarify the specific circumstances under which CMS will find that an agreement between a Biosimilar Manufacturer and a Reference

Manufacturer would disqualify a Biosimilar Manufacturer from making an Initial Delay Request. The commenters noted that a signed legal agreement between the Reference Manufacturer and the Biosimilar Manufacturer permitting the Biosimilar Manufacturer to market the Biosimilar may serve as evidence that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed. At the same time, however, for a Biosimilar Manufacturer to meet the requirements for CMS to grant an Initial Delay Request, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or that directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

Response: CMS does not believe that the two agreement types that the commenters raise conflict since it is possible to have an agreement that permits commercialization without either directly or indirectly restricting volume or incentivizing the Biosimilar Manufacturer to submit an Initial Delay Request. CMS reiterates that, consistent with section 1192(f)(2)(D)(iv)(II) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that either requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request, or that directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

Comment: A few commenters expressed concern that the timeline for submitting Initial Delay Requests is unreasonably accelerated and will jeopardize the accuracy of the requests and create a barrier to biosimilar competition, as the timeline effectively eliminates the additional runway for a Biosimilar competitor to come to market between the deadline on May 22, 2023 for a Biosimilar Manufacturer to submit the documentation for its Initial Delay Request and the selected drug list publication date on September 1, 2023. A few commenters also expressed concern that CMS will not permit the Biosimilar Manufacturer to supplement its Initial Delay Request, except if CMS requests follow-up information or if the Biosimilar Manufacturer would like to update CMS on the status of the Biosimilar application for licensure before 11:59pm PT on August 15, 2023. Commenters requested that CMS set the Initial Delay Request submission deadline as close as reasonably possible to the selected drug list publication date and permit broad supplementation of a timely request with late-breaking information.

Response: CMS thanks these commenters for their feedback and reiterates that the statute is clear that an Initial Delay Request submitted with respect to initial price applicability year 2026 must demonstrate that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025. The Initial Delay Request timeline therefore does not preclude a Biosimilar from coming to market between the deadline on May 22, 2023 for a Biosimilar Manufacturer to submit the documentation for its Initial Delay Request and the selected drug list publication date on September 1, 2023 (though CMS notes that if the Biosimilar launches between May 22, 2023 and September 1, 2023, then CMS may determine the Reference Drug is not a qualifying single source drug based on the process described in section 30.1 of this revised guidance). Further, the Initial Delay Request deadline has already been set as close to the selected drug publication date as is administratively feasible. CMS adopted this timeline under the authority granted to it in section 1192(f)(1)(B)(ii) of the Act to set the time, form, and manner of Biosimilar Delay requests, and has exercised this authority to establish a timeline

(which is described in section 30.3.1.4 of the revised guidance) that allows CMS to carefully review the Initial Delay Request documentation and, if applicable, to request follow-up information from the Biosimilar Manufacturer on its Initial Delay Request. The timeline ensures that CMS will have adequate time to review follow-up data and make a well-informed determination. Regarding commenters' requests that CMS permit broad supplementation of a timely request, CMS believes that the timeline described in section 30.3.1.4 allows Biosimilar Manufacturers sufficient opportunity to provide CMS with information during the Initial Delay Request process. CMS is not able to accommodate broad supplementation of an Initial Delay Request given the ambitious statutory deadlines for implementing the Negotiation Program for initial price applicability year 2026. CMS will consider adjusting the Initial Delay Request timeline for initial price applicability year 2027 in future guidance, if feasible.

Comment: A few commenters requested that CMS create a way for a Biosimilar Manufacturer to ascertain, before the Initial Delay Request deadline, whether a Reference Drug is likely to be selected for negotiation. One commenter recommended that CMS enable a Biosimilar Manufacturer to inquire with CMS in advance of the Initial Delay Request deadline. A couple of commenters requested that CMS update the Part D Drug Spending Dashboard more frequently or direct manufacturers to other sources of publicly available information to inform assessments of the likelihood that a Reference Drug will be selected for negotiation.

Response: CMS thanks these commenters for their feedback. CMS must complete all steps of the drug selection process with fidelity, including the identification of negotiation-eligible drugs using PDE data with dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. As described in section 30.2 of this revised guidance, to allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service during this 12-month period that Part D plans have submitted to CMS no later than 30 days after May 31, 2023, i.e., by June 30, 2023. Further, to ensure that a potential qualifying single source drug does not have generic or biosimilar competition, CMS will review PDE data for the 12-month period beginning August 16, 2022 and ending August 15, 2023, using PDE data available on August 16, 2023, as well as AMP data for the 12-month period beginning August 1, 2022 and ending July 31, 2023, using the AMP data available on August 16, 2023 for a given generic drug or biosimilar biological product for which a potential qualifying single source drug is the listed drug or reference product. CMS is, therefore, unable to disclose information regarding the selected drug list in advance of the selected drug publication date due to the ambitious statutory deadline for identifying selected drugs and publishing the selected drug list.

CMS appreciates feedback received on the Part D Drug Spending Dashboard. This dashboard allows for a longer claims runout to provide time for claims to be submitted, processed, and finalized than is possible for the data that CMS is statutorily required to use to identify and rank negotiation-eligible drugs. CMS recently announced that it plans to continue its annual updates to the Drug Spending Dashboards to provide the public with comprehensive data on trends related to drug spending for Medicare and Medicaid.[12]

[12] See: https://www.cms.gov/blog/cms-drug-spending-dashboards-and-inflation-reduction-act.

Comment: A couple of commenters asked that CMS notify each Biosimilar Manufacturer that submits an Initial Delay Request of the results of such request in advance of the selected drug publication date. These commenters requested that CMS establish a mechanism by which manufacturers can dispute CMS' determination.

Response: Ambitious statutory deadlines prevent CMS from providing each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2026 with advance notice of CMS' determination regarding its request prior to the selected drug list publication date. However, CMS will notify each Biosimilar Manufacturer of CMS' determination on or after September 1, 2023, but not later than September 30, 2023. CMS does not intend to establish a dispute resolution process for Initial Delay Requests.

Comment: One commenter was uncertain whether Appendix B of the initial memorandum includes conflicting information on whether CMS will accept Initial Delay Requests that are incomplete or not timely.

Response: CMS appreciates this request for clarity and confirms that CMS will not accept Initial Delay Requests that are incomplete or not timely. CMS directs readers to section 30.3.1.4 of this revised guidance, which includes a table providing a summary of key dates related to implementation of the Biosimilar Delay for initial price applicability year 2026 as specified in section 30.3.1 of this revised guidance. The deadline for a Biosimilar Manufacturer to email CMS regarding its intent to submit an Initial Delay Request for initial price applicability year 2026 was 11:59 p.m. PT on May 10, 2023.

Comment: One commenter inquired about Question 10 of Appendix B: Template for the Initial Delay Request Form. The commenter remarked that a Biosimilar may qualify for an Initial Delay Request if its section 351(k) BLA is accepted for filing by August 15, 2023. Given FDA's 60-day filing review, the section 351(k) BLA must be submitted no later than June 16, 2023. A Biosimilar Manufacturer that has not yet submitted its section 351(k) BLA by May 22, 2023, but intends to do so by June 16, 2023, must select option (D) on the form detailed in Appendix B of the initial memorandum. The commenter requested that, to guard against any inadvertent disqualification of such Initial Delay Requests, CMS should make clear that selecting this option does not preclude eligibility for the Initial Delay Request.

Response: Selecting option (D) on the form detailed in Appendix B of this guidance does not preclude eligibility for the Initial Delay Request. Biosimilar Manufacturers have until 11:59 p.m. PT on August 15, 2023, to update CMS on the status of the Biosimilar's application for licensure.

Comment: A couple of commenters urged CMS to favor policies that support a robust biosimilars market that drives down prices for patients but did not reference any specific policies. These commenters stated that CMS should consider how to mitigate potential unintended consequences that may disincentivize the development of biosimilars and hinder a robust biosimilars market.

Response: CMS firmly supports a robust biosimilars market and believes that the policies for implementing the special rule to delay selection and negotiation of biologics for biosimilar

market entry will help support biosimilar entry and price competition in the biosimilars market. CMS welcomes input on specific approaches to monitor for potential unintended consequences of these policies and may consider modifications if necessary to mitigate any unintended impact.

Medicare Drug Price Negotiation Program Agreement (Sections 40, 40.1, and 40.6)

Comment: One commenter commented that the statute defines manufacturer by reference to section 1847A(c)(6)(A) of the Act and requested that CMS clarify the definition of Primary Manufacturer as it pertains to the very broad statutory definition.

Response: CMS thanks this commenter for the recommendation. Section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug, and the phrase "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program. The best statutory interpretation is to interpret the term "manufacturer" as a single entity for the negotiation process, responsible for negotiating the maximum fair price for a given selected drug. As described in section 40 of this revised guidance and pursuant to section 1191(c)(1) of the Act, to the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" (referred to in this revised guidance as the Primary Manufacturer) of the selected drug.

Comment: Some commenters requested that CMS remove requirements related to Secondary Manufacturers because they view such requirements as inconsistent with CMS' past interpretation of the definition of "manufacturer" in Section 1927(k)(5) of the Act.

Response: CMS appreciates commenters' feedback. In previous interpretations of other provisions of the Act, CMS has expressed concern with burdening manufacturers with no relationship to the holder of an NDA / BLA. In this revised guidance, CMS reiterates its position to exclusively limit any requirements with respect to the terms of the Agreement to manufacturers listed on the NDA / BLA, or manufacturers that market the selected drug pursuant to an agreement with the Primary Manufacturer. Any requirements placed on the Primary Manufacturer by the Negotiation Program to address Secondary Manufacturer actions are solely related to its voluntarily assumed relationship.

CMS also notes that, under the Negotiation Program, Primary Manufacturers enter into an agreement to negotiate an MFP with CMS and to provide access to that MFP for the selected drug, including sales of the selected drug by Secondary Manufacturers. Harm to competition from Primary Manufacturers ensuring MFP availability in sales by Secondary Manufacturers is unlikely because the requirement to provide access to the MFP is mandated by the Negotiation Program and not imposed by the Primary Manufacturer, and because accepting that approach is a requirement of the Negotiation Program. Moreover, the Negotiation Program offers operational flexibility to manufacturers and would not restrict the Primary Manufacturer or Secondary Manufacturer(s) from offering the selected drug at a price lower than the MFP. For these reasons, applying the MFP to sales by Secondary Manufacturers is unlikely to create a situation inconsistent with the antitrust laws.

Comment: In connection with their feedback on the Secondary Manufacturer policies, a few commenters cited the provisions of a 2007 Medicaid Drug Rebate Program (MDRP) rule relating to the treatment of authorized generic drugs. A few commenters also cited a provision from a 2016 MDRP rule relating to the treatment of line extensions.

Response: CMS thanks these commenters for their input. This revised guidance echoes the relationship between manufacturers in the 2007 and 2016 MDRP rules. This revised guidance defines a Secondary Manufacturer as either listed as a manufacturer in the NDA or BLA or marketing the selected drug pursuant to an agreement with the Primary Manufacturer. As it relates to the comments regarding the 2016 MDRP rule, in which the primary concern expressed by commenters involves unrelated manufacturers, CMS notes that the initial memorandum focuses on Secondary Manufacturers with agreements with the Primary Manufacturer thereby limiting the applicability of those concerns. More generally, the 2007 and 2016 MDRP rules suggest that CMS has previously interpreted the statutory definition of "manufacturer" at section 1927(k)(5) of the Act to apply to situations involving multiple manufacturers in a manner that is consistent with the IRA initial memorandum policy of imposing obligations on a Primary Manufacturer with regard to Secondary Manufacturers. Where differences remain under which the Negotiation Program imposes more substantial obligations on the Primary Manufacturer for commercial practices and data of Secondary Manufacturers, these differences are supported by the text, scope, and purpose of the IRA.

Comment: One commenter questioned whether CMS' definition of Secondary Manufacturer could include firms that do not meet the statutory definition of manufacturer with respect to the selected drug but have a marketing agreement in place with the Primary Manufacturer.

Response: CMS thanks this commenter for their input. As described in section 40 of this revised guidance, for initial price applicability year 2026, CMS will refer to any entity other than the Primary Manufacturer that meets the statutory definition of manufacturer, under section 1191(c)(1) of the Act, for a drug product included in the selected drug, and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer, as a Secondary Manufacturer. Secondary Manufacturers will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meets these criteria, including those entities that have a marketing agreement with the Primary Manufacturer. A firm that does not meet the statutory definition of a manufacturer under section 1191(c)(1) of the Act does not meet CMS' definition of a Secondary Manufacturer.

Comment: Several commenters requested that CMS provide a comment period for the Medicare Drug Price Negotiation Program Agreement (herein referred to as the "Agreement") to allow manufacturers and the public the opportunity to review and comment on the Agreement. A few commenters expressed concern that lack of advance notice could result in a manufacturer's inability to establish appropriate processes prior to the Agreement's effective date, resulting in possible noncompliance. A couple of commenters also stated that there are only three options for manufacturers within the Negotiation Program under the IRA: sign the Agreement, pay the excise tax, or leave Medicare and Medicaid. Manufacturers expressed concern with the lack of options available to a manufacturer that chooses not to sign the Agreement.

Response: In section 40 of the initial memorandum, CMS included descriptions of and solicited comments on the Agreement requirements to provide interested parties an opportunity to comment on these requirements. Given the thoughtful and extensive comments CMS received on these requirements, CMS determined to set forth the parameters of the manufacturer's obligations under the Negotiation Program in this revised guidance, while reserving for the Agreement certain general provisions and term and termination provisions. The decision to not separately repeat the program requirements in the Agreement means that the program requirements applicable to a manufacturer of a selected drug that enters into an Agreement for initial price applicability year 2026 are preserved and presented in this revised guidance for which there has been public notice and comment. In light of the complexity of the actions the agency must undertake in advance of the Agreement being signed by the statutory deadline of October 1, 2023, CMS will not provide a comment period on the Agreement. However, CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list is published for initial price applicability year 2026. Please see the responses to comments below for a discussion of the options available to manufacturers who choose not to participate in the Negotiation Program.

Comment: One commenter asked that CMS provide manufacturers with information on how CMS plans to monitor compliance with the Agreement and allow for manufacturers to provide feedback on this information.

Response: The initial memorandum and subsequent revised guidance provide information on how CMS plans to monitor compliance with the Agreement, including the requirements within this revised guidance. As described in section 90.1 of this revised guidance, CMS will provide information about the negotiation process to the Primary Manufacturer of each selected drug. CMS anticipates this information will include operational and statutory timelines, procedural requirements, system instructions, IRA resources, and contact information. During the negotiation period, CMS plans to track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer, including as it relates to compliance. CMS is committed to supporting compliance with program requirements and will provide written reminders and warnings of potential noncompliance (described in section 90.1 of this revised guidance). Following the conclusion of negotiations, CMS plans to monitor compliance related to the Primary Manufacturer's obligations to provide access to the MFP, as described in section 40.4 and section 90.2 of this revised guidance.

As described in section 40.5 of this revised guidance, in monitoring compliance, CMS may engage in auditing processes to verify the accuracy and completeness of any information provided by the Primary Manufacturer, as well as any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by any Secondary Manufacturer(s).

Comment: A few commenters stated that CMS should not require Primary Manufacturers to submit points of contact for the Agreement within five calendar days of publishing selected drugs, as this process is not included in statute. Commenters noted that CMS should state its

authority in developing this timeline and clarify implications of noncompliance with this timeline.

Response: CMS thanks these commenters for their feedback. CMS revised its policy in section 40.1 of this revised guidance regarding providing points of contact. CMS recommends but does not require this action be taken within five days following publication by CMS on September 1, 2023 of the list of selected drugs and prior to the Agreement being signed to facilitate communication between CMS and the Primary Manufacturer and support efficient effectuation of the Agreement. Primary Manufacturers must provide points of contact by October 1, 2023 at the time that the Agreement is signed.

Comment: A few commenters suggested that CMS consider different ways to designate a Primary Manufacturer other than the holder of the NDA / BLA, given scenarios like split licensures and acquisitions. Commenters recommended CMS consider using the FDA product labeler ID to determine the manufacturer for purposes of negotiating the MFP.

Response: When an application to market a new drug or biological product for human use is submitted to the FDA, the NDA / BLA that is submitted lists only one sponsor. The policy for identifying the Primary Manufacturer with responsibility for the selected drug based on the holder of the NDA / BLA for the selected drug under the Negotiation Program is consistent with the FDA regulatory framework under which the single sponsor of the NDA / BLA in its application describes the manufacturing process and lists the facilities that will produce the sponsor's product. In section 1191(c)(1) of the Act, the statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. CMS understands that the holder of an NDA or BLA can enter into agreements regarding the sale of drugs approved under a particular NDA or BLA with other entities that may also meet this statutory definition of "manufacturer." CMS must find a mechanism to identify the appropriate manufacturer for purposes of negotiation and ensure other aspects of the Negotiation Program apply to the selected drug. In addition, section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug and the term "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program. The best statutory interpretation is to interpret the term "manufacturer" as a single entity for the negotiation process, responsible for negotiating the maximum fair price for a given selected drug. Thus, the most effective way to determine the "manufacturer" described in section 40 of this revised guidance, and the signatory of the Agreement, is to identify the NDA / BLA holder as the Primary Manufacturer.

Comment: Many commenters made recommendations pertaining to the Agreement and how it applies to Secondary Manufacturers. Commenters recommended CMS require all Secondary Manufacturers to sign the same Agreement that applies between Primary Manufacturers and CMS. A few commenters suggested that Secondary Manufacturers sign a unique Agreement with CMS in addition to the Agreement between Primary Manufacturers and CMS. A few commenters were supportive of CMS' policy to enter into an Agreement with only the Primary Manufacturer.

Response: Given that section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug to which "the manufacturer" would provide access in accordance with the statute, and given that the term "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program, the best statutory interpretation is to interpret the term "manufacturer" as a single entity for the negotiation process, responsible for negotiating a single maximum fair price for a given selected drug. Thus, in accordance with section 1193(a)(1) of the Act and other statutory references to "the manufacturer," CMS will enter into an Agreement with "the manufacturer" of a selected drug, where "the manufacturer" is the NDA / BLA holder as described in section 40 of this revised guidance. CMS has adopted the designations of "Primary Manufacturer" and "Secondary Manufacturer," respectively, to establish a process to negotiate the maximum fair price with "the manufacturer" to align with the meaning of the statutory language and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and MFP availability for the selected drug sold by the Secondary Manufacturer(s).

Comment: One commenter asked CMS to clarify whether a Primary Manufacturer is only responsible for data submission and MFP availability for sales of the selected drug by a Secondary Manufacturer when there is a contractual agreement between the two parties.

Response: CMS thanks this commenter for their question. For initial price applicability year 2026, a Primary Manufacturer will be responsible for data submission and MFP availability for sales of the selected drug by a separate manufacturer of the selected drug if that separate manufacturer is a Secondary Manufacturer as described in section 40 of this revised guidance. An entity is a Secondary Manufacturer if it meets the statutory definition of a manufacturer for the selected drug and either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer. Specifically, any manufacturer that qualifies as a Secondary Manufacturer for initial price applicability year 2026 will have an existing relationship with a Primary Manufacturer. A Secondary Manufacturer will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug.

Comment: A few commenters stated that CMS should allow each Secondary Manufacturer to participate in all negotiation activities, including negotiation meetings, and have access to all written correspondence between the Primary Manufacturer and CMS. If CMS chooses not to allow this, the Primary Manufacturer should be allowed to share any and all documentation with the Secondary Manufacturer.

Response: The best statutory interpretation is to interpret the term "the manufacturer" as a single entity for the negotiation process responsible for negotiating a single maximum fair price for a given selected drug. In addition, section 1193(a)(1) of the Act instructs CMS to negotiate with "the manufacturer" to arrive at the MFP for a given selected drug, and the phrase "the manufacturer" appears repeatedly throughout the statutory provisions establishing the Negotiation Program. Congress's use of the singular definite article demonstrates that, for any one selected drug, the "manufacturer" with which CMS negotiates is a single entity. Thus, CMS believes that the most effective way to determine the "manufacturer" described in section 40 of the guidance and the signatory of the Agreement, is to identify the NDA / BLA holder as the

Primary Manufacturer. CMS has adopted the designations of "Primary Manufacturer" and "Secondary Manufacturer," respectively, to establish a process to negotiate an MFP with a single manufacturer to align with the meaning of the statutory language "the manufacturer," and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and ensuring MFP availability for selected drug sold by the Secondary Manufacturer(s).

As described in section 40.2.2 and 60.6.1 of this revised guidance, CMS does not intend to publicly discuss the negotiation process prior to the public explanation of the MFP being released, unless a Primary Manufacturer discloses information that is made public. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. Primary Manufacturers engaged in negotiating an MFP with CMS are reminded that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. Primary Manufacturers should consider the antitrust implications of any such actions. CMS will protect the confidentiality of any proprietary information from Primary Manufacturers or Secondary Manufacturers (described in section 40.2.1) as required under section 1193(c) of the Act and other applicable law. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this revised guidance. Neither the IRA nor this revised guidance prevents Primary Manufacturers from disclosing any information to Secondary Manufacturers.

Comment: One commenter stated that CMS should revise the National Drug Rebate Agreement and the Coverage Gap Discount Program Agreement, and work with the Health Resources and Services Administration (HRSA) to revise the Pharmaceutical Pricing Agreement, to permit immediate termination from all applicable federal programs in the event that an agreement on an MFP cannot be reached or a manufacturer is dissatisfied with the MFP.

Response: CMS thanks this commenter for their recommendation. CMS has clarified in section 40.6 of the revised guidance that a Primary Manufacturer that decides not to participate in the Negotiation Program may voluntarily terminate the Medicare Drug Price Negotiation Program Agreement if it also ceases participation in the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program through the end of the price applicability period for the selected drug. CMS has also clarified in section 40.1 of the revised guidance that a Primary Manufacturer that elects not to participate in the Medicare Drug Price Negotiation Program may take similar measures to cease its participation in the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program. Sections 40.1 and 40.6, as revised, set forth the procedures for the Primary Manufacturer to initiate termination processes under the Medicare and Medicaid programs and the steps CMS will take to facilitate an expeditious termination of the Primary Manufacturer's agreements under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable. As a result of these procedures, any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax liability by submitting

the notice and termination requests described herein 30 days in advance of the date that excise tax liability otherwise may begin to accrue. Moreover, any manufacturer that has entered into an Agreement will retain the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability.

Manufacturer Data Submission, Proprietary Information, and Confidentiality (Section 40.2)

Comment: Several commenters requested that CMS not publish any proprietary information in the MFP public explanation and continue to provide strong protections to proprietary data otherwise collected under Part D. Several commenters also stated that CMS should give manufacturers the opportunity to review, raise concerns, and designate any information therein that is confidential and proprietary in advance of the publication of the public explanation of the MFP. A few commenters stated that CMS should clarify that any proprietary information shall be disclosed or exclusively used by CMS or the Comptroller General of the United States only for IRA-related purposes, and not used or disclosed for any other reason, regardless of whether the requirements of the Freedom of Information Act (FOIA) are satisfied.

Response: Section 1193(c) of the Act requires that information submitted to CMS by the manufacturer of a selected drug that is proprietary information, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. CMS is committed to protecting confidential and proprietary information obtained from manufacturers throughout the negotiation process. In addition, CMS is also committed to protecting information that is obtained from Prescription Drug Plans (PDPs) and MA-PD plans that will inform the negotiation process. For initial price applicability year 2026, as described in section 40.2.1 of this revised guidance, CMS will treat information on non-FAMP as proprietary, as well as treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with sections 1194(e)(1) and 1194(e)(2) of the Act as proprietary, if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that meets the requirements set forth under Exemptions 3 and/or 4 of FOIA (5 U.S.C. § 552(b)(3), (4)). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. § 1905 requires executive branch employees to protect such information. CMS understands commenters' concerns pertaining to the confidentiality of proprietary information and will protect confidential and proprietary information as required by applicable law. However, if a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this guidance.

Comment: Some commenters stated that CMS should remove, or at least modify, the data destruction requirements within the confidentiality policy for manufacturers following the deselection of a selected drug. One commenter stated that CMS should consider removing the 30-day timeline for data destruction, or let manufacturers petition for an extension. Other commenters stated that CMS should impose parallel data destruction requirements or revise the policy to align with other federal programs.

Response: After reviewing these comments and further consideration of the issue, CMS has removed the data destruction requirements under the confidentiality policy described in section 40.2.2 of this revised guidance pertaining to Primary Manufacturers.

Comment: Many commenters requested that CMS clarify whether specific data elements submitted by Primary Manufacturers (including, where applicable, Secondary Manufacturer data submitted by the Primary Manufacturer) will be released publicly. Commenters asked that CMS aggregate and release information about prior Federal financial support, approved patents, exclusivities, approvals, aggregate estimates or deidentified research and development costs, historic sales, volume of sales, revenue, and market data of selected drugs. Commenters requested that CMS clarify that information that is publicly available will not be deemed proprietary.

Response: CMS thanks these commenters for their input. As stated in section 40.2.2 of the revised guidance, CMS revised the confidentiality policy for the negotiation process in response to comments received and further consideration of the issue. In the interest of balancing transparency and confidentiality, CMS has made revisions in the guidance pertaining to what information CMS will keep confidential and for how long. As described in section 40.2.2 and 60.6.1 of this revised guidance, as a part of the public explanation of the MFP published in March 2025, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings. CMS maintains that any information submitted by manufacturers that constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer will be considered proprietary and will be redacted.

A Primary Manufacturer may choose to publicly disclose information regarding any aspect of the negotiation process at any time, including prior to the public explanation of the MFP being released by CMS. Of note, while CMS generally plans to wait to release information about the negotiation process until CMS publishes the public explanation of the MFP, if the Primary Manufacturer chooses to disclose information prior to the publication of the public explanation of the MFP, CMS may decide to make early disclosures about the negotiation process as well.

Comment: One commenter stated that CMS should clarify what elements of the Biosimilar Initial Delay Request will be exempt from any FOIA requests or disclosures.

Response: CMS revised section 30.3.1 of this revised guidance to clarify that information in an Initial Delay Request and in a Small Biotech Exception ICR Form that is a trade secret or confidential commercial or financial information will be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of FOIA (5 U.S.C. § 552(b)(3), (4)).

Comment: One commenter stated that CMS should clarify that the existence and status of a pending NDA or BLA, in addition to information contained in a pending NDA or BLA, will be treated as proprietary information.

Response: As stated in the initial memorandum, for initial price applicability year 2026, CMS will treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. It is CMS' presumption that a pending NDA or BLA would qualify as proprietary under this standard.

Comment: One commenter asked CMS to release the full negotiation records five to ten years after the patents for a selected drug expire.

Response: As stated in section 40.2.2 of this revised guidance, CMS revised the confidentiality policy for the negotiation process in response to comments received and after further consideration of the issue. In the interest of balancing transparency and confidentiality, CMS has made revisions in the guidance pertaining to what information CMS will keep confidential and for how long. As described in sections 40.2.2 and 60.6.1 of this revised guidance, as a part of the public explanation of the MFP published in March 2025, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings.

At this time, CMS is issuing guidance for implementation of initial price applicability year 2026 and does not foresee that CMS would subsequently provide additional disclosure in the manner the commenter is suggesting. CMS will continue to consider whether such additional disclosure is appropriate in the future.

Comment: One commenter asked CMS to clarify the consequences for violating the requirements of confidentiality for both manufacturers and CMS.

Response: CMS thanks this commenter for their input. In the interest of balancing transparency and confidentiality, CMS revised the confidentiality policy for the negotiation process in response to comments received and further consideration of the issue. CMS does not intend to publicly discuss the negotiation process prior to the public explanation of the MFP being released, unless a Primary Manufacturer chooses to discuss the negotiation publicly. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. Primary Manufacturers engaged in negotiating an MFP with CMS are reminded that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. Primary Manufacturers should consider the antitrust implications of any such actions.

The Trade Secrets Act at 18 U.S.C. § 1905 requires executive branch employees to protect proprietary information. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary

Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this revised guidance.

Comment: One commenter asked how CMS will enforce the confidentiality requirements for individuals who no longer work at a manufacturer of a selected drug or at CMS.

Response: CMS thanks this commenter for their question. In the interest of balancing transparency and confidentiality, CMS revised the confidentiality policy for the negotiation process in response to comments received and further consideration of the issue. Primary Manufacturers have the authority to determine how former employees may use or discuss its proprietary information as it pertains to the Negotiation Program. CMS employees that leave CMS are informed prior to their departure that they are not permitted to disclose nonpublic information obtained as a result of CMS employment that has not been released to the public.

Comment: Many commenters stated that the confidentiality policy as described in the initial memorandum violates the First Amendment rights of manufacturers, is not supported by statute, or is not necessary to administer or monitor compliance with the Negotiation Program. One commenter asked that CMS align the confidentiality policy so manufacturers and CMS are bound by the same confidentiality standards. Many commenters raised concerns that the confidentiality policy would prevent manufacturers from disclosing to their board and investors pertinent information related to the negotiation process. One commenter asked CMS to make all offers and counteroffers public. A few commenters were supportive of CMS' confidentiality policy as it is consistent with private sector negotiation processes.

Response: CMS thanks these commenters for their input. As stated in section 40.2.2 of the revised guidance, CMS revised the confidentiality policy for the negotiation process in response to comments received and upon further consideration of the issue. In the interest of balancing transparency and confidentiality, CMS has made revisions pertaining to which information CMS will keep confidential and for how long in the revised guidance. As described in sections 40.2.2 and 60.6.1 of the revised guidance, as a part of the public explanation of the MFP published in March 2025, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings. CMS maintains that any information submitted by manufacturers that constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer will be considered proprietary and will be redacted.

A Primary Manufacturer may choose to publicly disclose information regarding any aspect of the negotiation process at any time, including prior to the explanation of the MFP being released by CMS. Of note, while CMS generally plans to wait to release information about the negotiation process until CMS publishes the explanation of the MFP, if the Primary Manufacturer chooses to disclose information about the negotiation process prior to the publication of the public explanation of the MFP, CMS may decide to make early disclosures about the negotiation process as well. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer,

CMS will no longer consider that material proprietary consistent with section 40.2.1 of this revised guidance.

Comment: One commenter stated that CMS should allow manufacturers to negotiate the scope and terms of any confidentiality policies, including whether manufacturers may publicly discuss the Negotiation Program, as a part of the broader negotiation process.

Response: CMS thanks this commenter for their input. In the interest of balancing transparency and confidentiality, CMS made revisions in the guidance to clarify that a Primary Manufacturer may publicly disclose information regarding the Negotiation Program, as described in section 40.2.2 of this revised guidance. In section 40.2 of this revised guidance, CMS describes a confidentiality policy that applies to all Primary Manufacturers of selected drugs who choose to sign an Agreement. Adopting a standard confidentiality policy allows CMS to focus the negotiations on the statutory goal of negotiating to achieve agreement on the lowest MFP and creates uniform protection of information determined to be proprietary as well as transparency upon the release of the explanation of the MFP.

Comment: One commenter asked CMS to consider revising the policies for classification and handling of proprietary data in the coming years and re-evaluate whether this approach should be applied to a narrower set of data elements.

Response: CMS thanks this commenter for their input and will take the comment under advisement as CMS considers policies for future years of the Negotiation Program.

Comment: A few commenters asked how CMS plans to secure manufacturer-submitted data. Commenters asked CMS to outline a cybersecurity policy regarding how CMS plans to implement safeguards to protect manufacturer-submitted data, how such data will be stored, and a process for alerting manufacturers of any breach or erroneous use.

Response: CMS thanks these commenters for their comments on safeguarding data submitted by manufacturers. Primary Manufacturers will submit the information to CMS via the Health Plan Management System ("CMS HPMS"). The CMS HPMS adheres to all applicable policies, procedures, controls, and standards required by the Department of Health and Human Services (HHS)/CMS information security and privacy programs to ensure the confidentiality, integrity, and availability of manufacturer information and government information systems. The CMS HPMS system is the primary CMS system for exchange of information between CMS and Medicare Advantage and Medicare Prescription Drug Plans, and as such is designed to receive and keep confidential proprietary and commercially sensitive information.

As required by CMS, the CMS HPMS integrates security into every aspect of the system development life cycle. The CMS HPMS is subject to the agency's Security Assessment and Authorization (SA&A) process, a rigorous methodology during which the system must demonstrate a sound and comprehensive information security posture. In order to achieve and maintain an Authority to Operate (ATO), the CMS HPMS routinely undergoes system penetration testing as well as a Security Control Assessment (SCA), where independent auditors

perform a detailed assessment to ensure that the system's security controls meet the CMS Acceptable Risk Safeguards (ARS).

An individual must apply for and obtain a CMS-issued user account and password in order to access the CMS HPMS. In addition to the CMS-issued user ID and password, internal CMS staff must use an HHS identification badge (referred to as a PIV card) when accessing the website on the CMS network, while all users accessing the system from outside of the CMS network must use multi-factor authentication. The CMS HPMS further employs role-based access, ensuring that each user is granted access only to those functions required by their position.

The CMS HPMS is hosted at a CMS approved cloud service provider. The system is protected by a suite of firewall and intrusion detection services, including Akamai Content Delivery Network (CDN), which serves as an additional web application firewall that offers robust distributed denial of services protection and access control. The CMS HPMS utilizes a multi-zone architecture comprised of a presentation zone, an application zone, and a data zone, designed to provide further defense against security attacks. CMS will employ encryption at rest in the database for sensitive manufacturer data (e.g., proprietary information, including trade secrets and confidential commercial or financial information) in addition to encryption in transit.

The CMS HPMS adheres to the CMS Information Security Incident Handling Procedures, which are supplemented by the CMS HPMS Security Incident Handling Procedures. These documents outline the procedures for managing known or suspected security or privacy incidents, including, but not limited to, roles and responsibilities, escalation procedures, and guidelines for notifying impacted individuals or organizations.

Negotiation and Agreement to an MFP and Renegotiation in Later Years (Section 40.3)

Comment: One commenter noted that CMS has not outlined the specific conditions under which a renegotiation will occur in subsequent years.

Response: CMS thanks this commenter for the comment. This guidance includes details regarding the Negotiation Program for initial price applicability year 2026. CMS will provide additional information in the future for initial price applicability years 2027 and beyond, including renegotiation, which will be implemented for initial price applicability year 2028 and subsequent years, in accordance with the statute.

Access to the MFP (Sections 40.4 and 90.2)

Comment: One commenter expressed concern that the MFP would be adopted as a reference price by non-Medicare payers. For example, commercial plans and PBMs might use a selected drug's MFP to inform negotiations or to establish payment and reimbursement amounts for the selected drug outside of the Medicare program.

Response: The IRA directs CMS to negotiate an MFP for each selected drug for the Medicare program and requires the manufacturers of such drugs to make the MFP available to MFP-eligible individuals. As discussed in section 80 of this revised guidance, for initial price

applicability year 2026, Primary Manufacturers of selected drugs must provide access to the MFP for a selected drug to Medicare beneficiaries who use their Part D plan (including an MA-PD plan under Medicare Part C or an Employer Group Waiver Plan, but not a plan that receives the Retiree Drug Subsidy) if Part D coverage is provided under such plan for such selected drug. The Negotiation Program does not regulate payment rates by payers outside of the Medicare program (e.g., in the commercial markets). CMS will publish the MFP for each selected drug, as required by law. The MFP for each selected drug could be published by pharmaceutical pricing database companies and could be used by other payers for reimbursement and other purposes. Payers will continue to have discretion to consider Medicare payment rates among other considerations in establishing their own payment policies. CMS notes that Medicare already establishes and publishes payment rates for drugs under Part B using the Average Sales Price (ASP) methodology that may be used by other payers (such as state Medicaid programs), and Medicaid also publishes various pharmaceutical pricing benchmarks, such as the National Average Drug Acquisition Cost (NADAC) file and Federal Upper Limits (FULs) for multiple source drugs, that may be used by other payers.

Comment: Many commenters provided perspectives and recommendations regarding CMS' policies in the initial memorandum to monitor access to the MFP. Many commenters recommended CMS require manufacturers to use a retrospective MFP refund approach to adjust reimbursement to pharmacies, mail order services, and other dispensing entities for dispensing a selected drug to an MFP-eligible individual. Many commenters recommended CMS help effectuate a retrospective refund model by contracting with a third-party administrator (TPA) or clearinghouse to facilitate data and/or payment exchange between entities in the supply chain so pharmacies, mail order services, and other dispensing entities receive retrospective refunds in a timely manner. Many commenters recommended that, in contracting with a TPA, CMS include processes to allow manufacturers to avoid providing the 340B price and an MFP refund for the same unit(s) of a selected drug dispensed to an MFP-eligible individual.

Response: CMS thanks these commenters for the recommendations. CMS intends to engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between supply chain entities to verify eligibility of MFP-eligible individuals. CMS appreciates the value of the role an MTF could play in supporting the identification of selected drugs dispensed to MFP-eligible individuals to facilitate appropriate retrospective reimbursement by manufacturers. CMS is also exploring options to facilitate retrospective payment exchange between interested parties to help effectuate access to the MFP. CMS is committed to the goal of ensuring prompt payment to dispensers for pass through of the MFP, consistent with other prompt pay rules in Part D.[13] Pursuant to section 40.4 of this revised guidance, CMS requires that the MFP be passed through to dispensers within 14 days of the manufacturer receiving sufficient information to verify that an individual is eligible for access to the MFP. With respect to the establishment of a process to allow manufacturers to avoid providing a 340B price and an MFP for the same unit of drug, CMS understands the value of the identification of 340B units for the Negotiation Program and the Part D Drug Inflation Rebate Program. CMS intends to examine options with respect to identification of 340B units and intends to work with HRSA accordingly. CMS has revised sections 40.4 and 90.2 of this revised guidance to include further detail regarding access

[13] See 42 C.F.R. § 423.520, Prompt Payment by Part D Sponsors, which requires Part D sponsor payment to pharmacies within 14 days after receiving a Part D claim and determining that the Part D claim is a clean claim.

to the MFP and will provide more information in advance of initial price applicability year 2026.

Comment: Some commenters recommended that CMS define the amount of the MFP refund that is due from the manufacturers to the pharmacies. Some advocated for a retrospective "true up" payment from the manufacturer to the dispensing entity, using a standardized amount, such as the difference between a publicly reported pricing metric (such as WAC) and the MFP, rather than a dispensing entity's actual acquisition cost for the selected drug. One commenter recommended CMS use the annual non-FAMP as the standardized metric.

Response: CMS thanks these commenters for their recommendation. The majority of the comments received from supply chain entities on this topic, including manufacturers and pharmacies, supported the use of a standardized, published pricing metric to calculate the refund due from the manufacturer to the pharmacy or other dispenser for the pass through of the MFP. After reviewing the comments and further consideration of the topic, CMS is exploring the option of allowing manufacturers to use a standardized refund amount, such as the WAC of the selected drug minus the MFP (WAC-MFP). CMS plans to provide further information regarding this topic in technical guidance before initial price applicability year 2026.

Comment: Some commenters recommended CMS regularly monitor whether Primary or Secondary Manufacturers are compliant with the requirements of the Negotiation Program, including providing access to the MFP. One commenter recommended CMS create an online option and phone options for reporting violations related to access to the MFP with respect to MFP-eligible individuals. One commenter recommended CMS set a time limit to respond to individuals reporting violations, report the number of complaints CMS receives, and create an ombudsman to serve as a point of contact for individuals submitting complaints.

Response: CMS thanks these commenters for their recommendations, including those relating to the importance of having multiple avenues for reporting violations and timely resolution of investigating such complaints. As further described in sections 40.4 and 90.2 of this revised guidance, CMS will closely monitor the Primary Manufacturers' compliance with the terms of the Agreement and other aspects of the Negotiation Program, including whether the Primary Manufacturer is ensuring that the MFP is available for the selected drug sold by Secondary Manufacturers, where applicable. CMS will establish procedures by which individuals, as well as pharmacies, mail order services, and other dispensing entities, will be able to report instances to CMS in which the MFP should have been made available but was not. CMS will respond to reports of violations in a timely manner, and plans to issue more information on reporting procedures in advance of initial price applicability year 2026.

Comment: A few commenters recommended that CMS establish a financially viable model for pharmacy reimbursement when a pharmacy dispenses a selected drug to an MFP-eligible individual, including by requiring a dispensing fee that covers a pharmacy's business operation costs to dispense a selected drug. A couple of commenters recommended that CMS clarify that claims paid for a selected drug must be excluded from pharmacy DIR or other fees imposed by entities in the supply chain. A couple of commenters recommended CMS prohibit PBMs, Part D plan sponsors, or other entities in the supply chain from charging administrative fees to

manufacturers or pharmacies for providing access to a selected drug. One commenter recommended CMS require higher dispensing fees for entities dispensing a selected drug.

Response: CMS thanks these commenters for their recommendations. Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for such drug. CMS intends to allow manufacturers to use either a prospective upfront discount model or a retrospective refund model to make the MFP available. After reviewing the comments and further consideration of the topic, CMS is working with interested parties to explore developing a standard retrospective rebate model process that would allow for the pass through of the MFP for a selected drug by manufacturers to dispensing entities for dispensing a selected drug to an MFP-eligible individual. As noted above, CMS intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to verify eligibility of MFP-eligible individuals under a retrospective rebate model. As described in section 40.4 of this revised guidance, neither Primary Manufacturers nor their contracted entities shall charge any transaction fee to dispensing entities for the pass through of the MFP to the dispenser.

Provided that Part D plans comply with all applicable requirements, plan sponsors retain flexibility in determining the fees paid or charged to pharmacies, including dispensing fees. However, CMS is committed to the goal of assuring prompt payment to pharmacies and other dispensers for passing through the MFP, consistent with other prompt pay rules in Part D, and is requiring manufacturers to pass through the MFP within 14 days of confirming an individual is eligible for the MFP. Please refer to sections 40.4 and 90.2 of this revised guidance for more information.

Comment: Some commenters recommended CMS collaborate with interested parties to implement a single process for manufacturers to provide access to the MFP that works for entities across the pharmaceutical supply chain. A few commenters recommended CMS work with interested parties in the pharmaceutical supply chain to develop standards for facilitating the transaction of the MFP refund.

Response: CMS thanks these commenters for their recommendations. Consistent with section 40.4 of this revised guidance, Primary Manufacturers must provide access to the MFP by either (1) ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP, or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. However, CMS notes that the majority of the commenters support the retrospective rebate or refund approach. CMS intends to engage with an MTF that could assist with data facilitation in a retrospective rebate model. CMS has been working with, and plans to continue working with, interested parties to explore processes for facilitating data exchange while minimizing burden.

Comment: A few commenters supported the options CMS outlined in the initial memorandum for providing access to the MFP. One commenter recommended CMS incentivize manufacturers to prospectively effectuate access to the MFP by making the MFP available to dispensing entities at the point of acquisition of a selected drug. One commenter recommended CMS require

manufacturers to create secondary NDCs for selected drugs and make secondary NDCs available to wholesalers at the MFP.

Response: CMS thanks these commenters for their recommendations. The majority of commenters supported a retrospective refund or rebate approach to making pharmacies, mail order services, and other dispensers whole with respect to the pass through of the MFP. CMS intends to engage with an MTF to help facilitate data exchange to confirm MFP-eligibility to provide access to the MFP using a retrospective approach for pharmacies, mail order services, and other dispensers. CMS is not requiring manufacturers to create secondary NDCs for selected drugs and the assignment of labeler codes is the responsibility of the FDA. Moreover, the NDCs for the dosage forms and strengths of a selected drug will be published on the CMS website, and CMS expects that pharmaceutical drug pricing compendia will also publish them.

Comment: Some commenters recommended CMS share detailed Part D claims data with manufacturers to verify that an individual is eligible to receive a selected drug at the MFP. One commenter recommended CMS minimize the data shared with manufacturers and other entities in the supply chain while facilitating access to the MFP.

Response: CMS thanks these commenters for their recommendations. CMS agrees that a Primary Manufacturer should be able to verify that a selected drug was dispensed to an MFP-eligible individual. As further described in sections 40.4 and 90.2 of this revised guidance, after consideration of the comments, CMS plans to release more information in advance of initial price applicability year 2026 regarding how CMS might support and facilitate data exchange between pharmaceutical chain entities.

Comment: A couple of commenters recommended that CMS require Primary Manufacturers to report the MFP of a selected drug and the effective date for the MFP in standard drug pricing compendia.

Response: CMS thanks these commenters for their recommendation. CMS will publish the MFP at the per-unit level for the dosage forms and strengths for a selected drug and keep this list up-to-date over time on the CMS IRA website. CMS anticipates that various drug pricing compendia will decide to include the MFP in their pricing files.

Comment: Some commenters recommended CMS remove or lengthen the requirement for retrospective payment to dispensing entities be made within 14 days, due to operational complexities. Some commenters recommended CMS clarify that the 14-day reimbursement requirement begins when the claim is verified for an MFP-eligible individual. One commenter recommended that CMS clarify that the 14-day reimbursement period begins when the Primary Manufacturer receives the request for reimbursement.

Response: CMS thanks these commenters for their recommendations. CMS will apply the standards set forth in current Part D prompt pay reimbursement regulations regarding payment by plan sponsors to pharmacies to manufacturers for their pass through of the MFP for selected drugs. That is, CMS will require that a Primary Manufacturer ensure that pharmacies, mail order services, and other dispensers are reimbursed timely for the pass through of the MFP within 14

days of verifying eligibility of an MFP-eligible individual. This will ensure that pharmacies are paid for the claim for the selected drug in the same timeframe as if the entire claim would have been filled through the regular Part D process. Please see sections 40.4 and 90.2 of this revised guidance for more information.

Comment: Many commenters made recommendations regarding CMS policy relating to non-duplication of the MFP and the 340B ceiling price. One commenter recommended CMS clarify that the same unit(s) of a drug dispensed to an MFP-eligible individual is not eligible for a duplicate 340B discount. A few commenters wrote that it is burdensome for pharmacies and dispensing entities to identify 340B units proactively or retroactively to avoid duplication of the MFP and 340B ceiling price. Some commenters recommended CMS contract with a TPA to identify 340B units at the point of sale or during retrospective reimbursement. A few commenters recommended CMS condition claims payment for units of selected drugs on including an accurate 340B or non-340B claim modifier. A few commenters recommended CMS work with HRSA to ensure the MFP for a selected drug is not applied to a drug that was acquired at the 340B ceiling price. Some commenters recommended CMS implement an oversight system to audit selected drug units dispensed at the MFP and identify if the same units of a selected drug were acquired at the 340B ceiling price.

Response: CMS thanks these commenters for their recommendations. CMS reiterates, as described in section 40.4.1 of the initial memorandum, that a manufacturer that provides an MFP for a unit of a selected drug is not also required to provide a 340B discount on that same drug if the MFP is lower than the 340B ceiling price (and vice versa, that the MFP does not need to be made available if the 340B ceiling price is lower). That is, these price concessions are not cumulative.

Further, CMS understands the interest in ensuring compliance with the statutory requirement to avoid duplication of the MFP and the 340B ceiling price for a selected drug. CMS also notes the interest in requiring that all Part D claims be marked as either 340B or non-340B to ensure that there is no duplication of 340B prices with the pass through of the MFP. At this time, CMS is examining options with respect to identification of 340B units in consultation with HRSA and interested parties. In addition to any policies or procedures that CMS may adopt in this regard, CMS will also work with HRSA to ensure the MFP is made available where appropriate in a nonduplicated amount to the 340B ceiling price.

Comment: A few commenters recommended CMS create accessible materials that list the MFP for a selected drug and the date the MFP applies for Medicare beneficiaries to reference to understand access to the MFP. A few commenters recommended CMS incorporate information about the MFP of a selected drug into various beneficiary outreach materials.

Response: CMS thanks these commenters for their recommendations. CMS is committed to helping Medicare beneficiaries understand access to a negotiated MFP for a selected drug during the price applicability period. CMS will publish on its website the MFP at the per unit (e.g., tablet) level for each NDC-11 associated with the selected drug. CMS will also develop accessible materials to educate Medicare beneficiaries, as well as the health care providers and other organizations that serve them, on benefits related to the Negotiation Program.

Comment: One commenter recommended CMS reduce the need for Primary Manufacturers to retain any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers for units of selected drug. The commenter recommended CMS reduce the timeframe from ten years to six years from the date of sale due to the burden and costs associated with retaining these records.

Response: CMS thanks this commenter for the recommendation. CMS believes ten years is a reasonable requirement for record retention for these sales to align with the statute of limitations period under the False Claims Act.[14]

Suggestion of Error and Corrective Actions and Compliance (Sections 40.2.3 and 40.5)

Comment: Some commenters asked CMS to consider a dispute resolution process for any disputes on claims-level data, including 340B claims. A few commenters suggested that CMS delay reimbursement during any dispute resolution process. A few commenters suggested that if CMS does not create a dispute resolution process, that CMS develop stewardship principles within the Negotiation Program, including for facilitating access to the MFP.

Response: CMS thanks these commenters for their recommendations. CMS notes that it intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to support the verification of dispensing of a selected drug to an MFP-eligible individual. CMS believes that engaging with an MTF to facilitate data transfer for eligibility purposes could minimize the potential for claims-level disputes. With respect to the Primary Manufacturer's obligation to provide access to the MFP, requirements are described in sections 40.4 and 90.2 of this revised guidance. CMS is also providing Primary Manufacturers with a corrective action process, detailed in section 40.2.3 of this revised guidance.

Comment: A few commenters asked that CMS establish a dispute resolution process that would apply to various aspects of the Negotiation Program. One commenter asked that the dispute resolution process be established prior to the September 1, 2023, deadline for publication of selected drugs.

Response: CMS thanks these commenters for their recommendations. Section 1198 of the Act prohibits administrative or judicial review of CMS' determinations of drug selection, unit determination, and the determination of MFP. CMS recognizes that Primary Manufacturers, at times, may disagree with CMS regarding certain calculations during the negotiation process. Therefore, if a Primary Manufacturer in good faith believes that CMS has made an error in the calculation of the ceiling for the selected drug or the computation of MFP across dosage forms and strengths, section 40.5 of this revised guidance notes that the Primary Manufacturer can submit a suggestion of error. Additionally, sections 40.2.3 and 100.2 of this revised guidance have been revised to provide an opportunity for corrective action in certain circumstances in which a violation of a requirement could result in a CMP being issued.

[14] 31 U.S.C. § 3731(b).

Comment: A commenter asked that CMS allow for broader stakeholder input in any dispute resolution process that is created.

Response: CMS thanks the commenter for their recommendations. After considering feedback from multiple interested parties for initial price applicability year 2026, CMS updated section 40.5 of this revised guidance to allow Primary Manufacturers the opportunity to suggest potential errors to CMS in the event that the Primary Manufacturer has a good faith belief that CMS has made an incorrect calculation. Further, CMS updated section 100.2 of this revised guidance to describe how Primary Manufacturers will have an opportunity to correct identified incompleteness or inaccuracies in certain manufacturer-submitted information in instances in which a violation of a data submission requirement could result in the imposition of a CMP. CMS will continue to evaluate those processes for future years.

Other Provisions in the Agreement (Section 40.7)

CMS solicited comment on this section, but did not receive any comments that are not otherwise addressed elsewhere (see the Medicare Drug Price Negotiation Program Agreement (Sections 40, 40.1, and 40.6) section above).

Negotiation Factors (Section 50)

Comment: Many commenters supported the use of certain cost-effectiveness measures to gain insight into the relationship between cost and effectiveness for a selected drug and its therapeutic alternative(s). Cost-effectiveness measures mentioned by commenters included Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), and Health Years in Total (HYT) and alternative methods recommended for assessing cost-effectiveness included Generalized Risk-Adjusted Cost-Effectiveness (GRACE) and Generalized Cost-Effectiveness Analysis (GCEA). Some commenters recommended convening experts to advise CMS on whether such metrics or methods are appropriate for assessing clinical benefit within the context of negotiation. Some commenters requested CMS clarify that the use of such measures is permitted when evaluating clinical benefit.

Response: CMS appreciates these commenters' responses and suggestions. CMS indicates in section 50.2 of this revised guidance that CMS will review cost-effectiveness measures and studies that use such measures for initial price applicability year 2026 to determine if such measures are permitted under section 1194(e) of the Act. CMS may use content in a study that uses a cost-effectiveness measure if it determines that the cost-effectiveness measure used is permitted in accordance with the law. A measure will not be used to adjust the initial offer if the measure does not provide information related to the negotiation factors described in section 1194(e) of the Act or is used in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than the life of an individual who is younger, nondisabled, or not terminally ill, in accordance with section 1194(e)(2) and section 1182(e) of Title XI of the Act. CMS clarifies in this revised guidance that it will not use Quality-Adjusted Life Years (QALYs) to determine any offer.

Comment: Many commenters interpreted the initial memorandum as stating a CMS decision not to use QALYs when assessing clinical benefit of a selected drug and its therapeutic alternative(s) and supported such a decision.

Response: CMS appreciates these commenters' feedback and reaffirms that QALYs will not be used in the Negotiation Program. CMS will consider studies that use QALYs only when they contain other content that is relevant and permitted under section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act.

Comment: Some commenters urged CMS not to use any metrics of cost-effectiveness or clinical effectiveness because the metric and/or the underlying data or assumptions used to develop the metric may be discriminatory. Some commenters stated that CMS should adopt a full prohibition on the use of QALYs and/or "similar measure[s]" under the relevant prohibition in the Patient Protection and Affordable Care Act.

Response: CMS reaffirms that QALYs will not be used in the Negotiation Program to adjust CMS offers. In response to feedback received on whether any measures may be permissible under section 1194(e)(2) and section 1182(e) of Title XI of the Act, CMS revised section 50.2 of this revised guidance to indicate CMS will review and consider cost-effectiveness measures and studies that use such measures for initial price applicability year 2026. However, while such measures may be reviewed, they will not be used to adjust the initial offer if the measures do not provide information related to the negotiation factors described in section 1194(e) of the Act or are prohibited under section 1194(e)(2) of the Act, or under section 1182(e) of the Act.

Comment: Regarding CMS' intent to use data that can be separated from the use of QALYs within a given study, a couple of commenters requested clarification on how CMS would separate such evidence from QALYs. A few commenters requested that CMS not consider any study referencing QALYs in determining the initial offer.

Response: Per section 1194(e)(2) of the Act, comparative clinical effectiveness research may not be used "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." CMS will not, per section 1182(e) of Title XI of the Act, use QALYs but may review the underlying data, results, or other content in studies that employ QALYs. By doing so CMS may glean important insights into the outcomes associated with the drug under consideration. For example, a study using QALYs to examine the cost-effectiveness (i.e., reviewing the cost per outcome) of drug A compared to drug B for the treatment of cardiovascular disease will describe the population of interest and quantify the outcomes. Factors in the study that do not treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or terminally ill, such as demographic information, blood pressure, cardiovascular events, and mortality before and after starting drug A versus starting drug B may provide important data to CMS about the clinical benefit of drug A when compared to drug B. Reviewing demographic information and outcomes, such as in this example, does not require CMS to review the results of the QALY calculation but may still provide important clinical information.

This approach aligns with CMS' decision to not use QALYs in the Negotiation Program while also enabling CMS to review and consider relevant information.

Comment: Many commenters requested that CMS simplify the process by which the public, including patients and caregivers, can submit information on the negotiation factors described in section 1194(e)(2) of the Act and the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW). Commenters requested additional time for submissions and clarity on the format in which information should be submitted to ensure usability for the submission of factors related to sections 1194(e)(1) and 1194(e)(2) of the Act.

Response: CMS appreciates commenters' feedback. Due to the statutory timeline of the negotiation period, including the requirement under sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act for CMS to issue an initial offer by February 1, 2024, it is not feasible to extend the timeframe for the submission of information under section 1194(e)(2) of the Act. However, as described in section 60.4 of this revised guidance, CMS will host patient-focused listening sessions that will be open to the public, including patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties, to share patient-focused input on the therapeutic alternative(s) and other section 1194(e)(2) information regarding selected drugs. These patient-focused listening sessions will occur in Fall 2023 after the section 1194(e) data submission, which will give patients and other interested parties additional time to prepare their feedback. Regarding the standardization of submissions, CMS expects a wide range of data to be appropriately submitted as part of the process and does not seek to limit the types of data submitted based on format. CMS will review submissions in alignment with sections 50 and 60 of this revised guidance.

Comment: Some commenters supported CMS' decision to open the submission of section 1194(e)(2) factors to the public. Some commenters suggested evaluating bias in information submitted or requiring a conflict of interest disclosure.

Response: CMS appreciates commenters' feedback. As described in section 50.2 of this revised guidance, CMS will consider, among other factors, the source of information, whether the study has been through peer review, as well as risk of bias during review. CMS also requires that declarative statements submitted via the Negotiations Data Elements ICR be supported by cited evidence unless the submission is a description of personal experience. This approach focuses on the merit of the information provided.

Comment: One commenter suggested requiring an executive summary of manufacturer-submitted data and another suggested requiring manufacturers to report rebates at the drug level.

Response: CMS appreciates commenters' suggestions. The comment suggesting that CMS require an executive summary of manufacturer-submitted data is out of scope for the Negotiation Program guidance and will be considered for the revised Negotiation Data Elements ICR. Regarding the comment suggesting manufacturers be required to report rebates at the drug level, CMS consulted with subject matter experts and representatives of the pharmaceutical and biotechnology industry in developing the definitions described in Appendix C of this guidance to align with statutory data collection requirements and other federal programs.

Comment: A few commenters suggested that CMS validate manufacturer data using independent data sources or suggested a third-party entity validate manufacturer data instead of CMS. One commenter recommended that CMS specify that submissions may be audited to ensure accuracy.

Response: CMS will validate manufacturer-submitted data to the extent possible, including via audit as deemed appropriate, pursuant to compliance monitoring activities under section 1196(b) of the Act.

Comment: Some commenters stated that the Negotiation Data Elements ICR included unclear expectations or data formatting inconsistent with current manufacturer approaches to tracking such data. A few commenters stated this could generate risk for the manufacturer and that a standard data format should be clarified. One commenter requested that CMS clarify that only the Primary Manufacturer is responsible for submitting data on factors described in section 1194(e)(1) of the Act.

Response: The Primary Manufacturer is responsible for providing manufacturer-submitted data described in section 1194(e)(1) of the Act and section 50.1 of this revised guidance. More information on what must be reported can be found in Appendix C of this revised guidance. Comments on formatting are out of scope for the Negotiation Program guidance and will be considered in the revised Negotiation Data Elements ICR.

Comment: A couple of commenters requested that CMS accept any information provided by a manufacturer of a selected drug even if such information is not tied to a specific statutory factor.

Response: CMS will accept information as outlined in this revised guidance and the Negotiation Data Elements ICR in accordance with statutory requirements.

Comment: One commenter requested manufacturer data submissions be provided to CMS on a rolling basis to permit adequate time to compile accurate and complete data given the relationship between inadequate submissions and CMPs. Another commenter requested sufficient time for manufacturers to evaluate requests for information and price offers from CMS before a manufacturer is determined to be noncompliant and/or enforcement actions are taken. This commenter suggested that CMS has flexibility to establish the timeframe between publication of the selected drug list (September 1, 2023 for initial price applicability year 2026) and submission of data required under section 1194(e) of the Act (stated in the initial memorandum as October 2, 2023), particularly given the resulting tax liability for failure to submit data.

Response: CMS appreciates commenters' concerns regarding deadlines. Pursuant to sections 1191(d)(5)(A) and 1194(b)(2)(A) of the Act, Primary Manufacturers must submit the manufacturer-specific data described in sections 1193(a)(4)(A) and 1194(e) of the Act to CMS by October 2, 2023 for initial price applicability year 2026. CMS will use data submitted by the Primary Manufacturer and other interested parties when developing the initial offer for a selected

drug along with CMS analyses and assessments of evidence as described in section 50.2 of this guidance. CMS is abiding by the statutory deadlines in this revised guidance.

Comment: One commenter requested that CMS clarify that consideration of manufacturer average net unit price will not trigger a future renegotiation of MFP.

Response: Renegotiation is out of scope for this revised guidance for initial price applicability year 2026 and will be addressed in future guidance or rulemaking, as appropriate.

Establishment of a Single MFP for Negotiation Purposes (Section 60.1)

Comment: Some commenters expressed concern with CMS' proposal to use a 30-day equivalent supply to apply the MFP across dosage forms and strengths, particularly for drugs with irregular intervals, topicals, and drugs taken for acute symptoms. Some commenters requested that CMS provide alternative options, consult with manufacturers on the methodology to be used for a selected drug, and/or work with interested parties to better understand how 30-day equivalent supplies are calculated for those medicines that have irregular or varied dosing schedules.

Response: CMS appreciates commenters' feedback and requests for clarity. This revised guidance provides additional detail about how CMS will use the days' supply field in PDE data to calculate 30-day equivalent supply using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) when calculating the MFP ceiling (described in section 60.2 of this revised guidance) and using the WAC ratio for initial price applicability year 2026 to apply the MFP across dosage forms and strengths (described in section 60.5 of this revised guidance). For purposes of weighting across dosage forms and strengths, CMS believes that calculating a 30-day equivalent supply, using the days' supply field, is feasible for the high-expenditure, single source Part D drugs that might be subject to negotiation for initial price applicability year 2026. As described in section 60.3.2 of this revised guidance, when comparing prices of the therapeutic alternative(s) for purposes of informing a starting price for the initial offer, CMS may use an alternative methodology for calculating a 30-day equivalent supply when appropriate.

Limitations on Offer Amount (Section 60.2)

Comment: A few commenters opposed the approach described in the initial memorandum, which these commenters asserted would result in the ceiling being applied twice. One commenter agreed with CMS that an MFP should be calculated specific to dosage forms and strengths and account for the variation in prices "specific to each dosage form and strength of the selected drug," but proposed negotiating multiple MFPs per drug by calculating the ceiling for the lowest unit of measure of a selected drug and establishing a metric from which CMS may negotiate a percent of the MFP ceiling to arrive at the published MFP per lowest unit of measure.

Response: CMS appreciates commenters' feedback. CMS disagrees that the procedure that it described in the initial memorandum would have applied the MFP ceiling twice. However, after consideration of the comments, for initial price applicability period 2026, CMS has revised section 60.2 of the guidance to use the single ceiling per 30-day equivalent supply across all

dosage forms and strengths of the selected drug. This approach aligns with the concept of negotiating an MFP for a whole selected drug across multiple dosage forms and strengths (as identified on the list of NDC-11s of the selected drug in the CMS HPMS, per section 40.2 of this revised guidance) subject to a single MFP ceiling, and then applying that MFP across dosage forms and strengths as required under section 1196(a)(2) of the Act. As discussed in the response to comments under section 60.5 below, CMS intends to monitor the practical effect of its procedures for applying the MFP across the dosage forms and strengths of the selected drug to inform its use of its section 1196(a)(2) authority for initial price applicability years after 2026.

Comment: A few commenters recommended that CMS revise the non-FAMP calculation to use the four quarters of the fiscal year, as opposed to the calendar year, to align with the Veterans Health Care Act of 1992 and reduce burden on manufacturers. Relatedly, commenters recommended that CMS develop mechanisms to account for anomalies in the non-FAMP and to permit restatements of the average non-FAMP due to data or other errors identified after the fact.

Response: Section 1194(c)(6) of the Act defines average non-FAMP to mean "the average of the non-Federal average manufacturer price... for the 4 calendar quarters of the year involved." As a result, the statutory language requires that the calendar year be used to calculate the average non-FAMP. CMS has revised the definition of non-FAMP in Appendix C to clarify that any restatements of the non-FAMP made in any applicable manufacturer non-FAMP submissions to the Department of Veterans Affairs (VA) must be reflected in the non-FAMP submitted to CMS as part of the section 1193(a)(4)(A) manufacturer data submission. Section 50.1.1 and Appendix C of this guidance discuss how manufacturers should report non-FAMP to CMS in cases where there are no data or data are insufficient to calculate non-FAMP for at least one calendar quarter of 2021.

Comment: A few commenters requested clarification as to whether the time period for determining if a selected drug is an extended or long-monopoly drug runs to the start of the applicable initial price applicability year or selected drug publication date. Commenters noted that the initial memorandum is inconsistent, applying the length of time one way when describing the initial delay request made by a biosimilar manufacturer (i.e., to the start of the initial price applicability year) and another when determining the monopoly type as well as the applicable percent specified for the purposes of establishing a ceiling (i.e., to the selected drug publication date).

Response: CMS thanks these commenters for their careful review of the initial memorandum and appreciates their flagging this inconsistency. CMS has revised section 60.2.3 of this guidance to clarify that the time period for determining whether a selected drug is an extended- or long-monopoly drug runs to the start of the applicable initial price applicability year, as specified in sections 1194(c)(4)(A) and 1194(c)(5)(A) of the Act, respectively. However, CMS notes that, as discussed in section 60.2.3 of this guidance, the definition of "extended-monopoly drug" under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030. CMS interprets this to mean that no selected drug will be considered an extended-monopoly drug for purposes of calculating the ceiling prior to initial price applicability year 2030.

Comment: A couple of commenters requested that CMS clarify whether unit refers to non-FAMP units or PDE units in the calculation of the annual non-FAMP for the dosage forms and strengths of the selected drug.

Response: CMS thanks these commenters for their careful review of the initial memorandum and appreciates the requests for clarification. CMS has revised section 60.2.3 of this guidance to clarify that PDE units will be used when averaging non-FAMP across NDC-11s. This is consistent with the use of PDE units to average NDC-9[15] non-FAMP amounts to a whole drug non-FAMP amount.

Comment: A few commenters disagreed with CMS' intent to use DIR data in calculating the "sum of the plan-specific enrollment weighted amounts" for purposes of determining the MFP ceiling. These commenters claim that the "plan specific enrollment weighted amount" is defined by reference to the Part D negotiated price, which does not include price concessions from manufacturers.

Response: Section 1194(c)(2)(A) of the Act states that the "plan-specific enrollment weighted amount" for a Part D or MA-PD plan with respect to a covered Part D drug is calculated using the negotiated price of the drug under the plan "net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan," and as such CMS plans to use DIR data, including information on manufacturer rebates and other price concessions collected through DIR reporting, in calculating the "sum of the plan-specific enrollment weighted amounts" under section 1194(c)(1)(B) of the Act.

Comment: One commenter recommended that CMS provide manufacturers with an opportunity to review and reconcile CMS' data for the MFP ceiling calculation for a selected drug. One commenter expressed concern that CMS is engaging in various conversion calculations to move from data at the NDC-11 level to the NDC-9 level to the whole drug level without providing sufficient detail to interested parties.

Response: CMS appreciates commenters' feedback. As discussed in section 60.4 of this revised guidance, CMS will provide the Primary Manufacturer information on the calculation of the statutorily-determined ceiling price. However, CMS is not able to provide manufacturers with all data used in ceiling calculations, as some of the calculations use proprietary information.

Comment: One commenter suggested that CMS should consider that the manufacturer-specific factors in section 1194(e)(1) of the Act could constitute the floor for price negotiations while the factors in section 1194(e)(2) could constitute the ceiling, keeping in mind the statutory ceiling in section 1194(c).

Response: As the commenter notes, section 1194(c) of the Act provides a specific formula for the calculation of the ceiling on the MFP for a selected drug, which is further described in section 60.2 of this guidance. The statute also requires CMS to consider the nine factors

[15] In this guidance, the NDC-9 refers to the first two segments of the NDC-11 that represent the labeler code and product portions of the NDC and indicate a drug's dosage, form, and strength regardless of the package size.

described in sections 1194(e)(1) and 1194(e)(2) when developing the initial offer. The statute does not direct CMS to use the manufacturer-submitted data or the section 1194(e)(2) data to establish a floor or ceiling, respectively, for price negotiations.

Methodology for Developing an Initial Offer (Section 60.3)

Comment: Many commenters recommended that CMS set the initial offer at or near the ceiling for all or a subset of selected drugs; for example, drugs that have provided therapeutic advancements, filled an unmet need, or otherwise demonstrated significant patient benefit; drugs under patent protection; small molecule drugs; and all drugs for initial price applicability year 2026 and for several subsequent price applicability years thereafter.

Response: CMS appreciates commenters' input. Section 1194(b)(1) of the Act instructs CMS to develop and use a consistent methodology and process for negotiations that aims to achieve agreement on the lowest MFP for each selected drug and in doing so, to consider the nine factors described in sections 1194(e)(1) and 1194(e)(2) of the Act. Offering the ceiling without a more thorough review of those statutory factors, including manufacturer-submitted data, may not achieve that objective and is inconsistent with the statutory directive.

Comment: CMS received many comments related to the identification of therapeutic alternative(s). Some commenters expressed concern regarding CMS' intent to use the price of the therapeutic alternative(s) in developing the offer starting point, including that drugs would be identified as the therapeutic alternative(s) based on cost rather than clinical appropriateness and that patients' needs will be overlooked when identifying the therapeutic alternative(s). A few commenters also noted that drugs in certain classes have few equivalent or substitutable alternatives. Some commenters were generally supportive of CMS' approach to identifying the therapeutic alternative(s), including limiting comparators to pharmaceutical alternatives, identifying therapeutic alternative(s) by indication, and considering off-label use when appropriate. However, a few commenters opposed CMS' approach to consider off-label use when identifying the therapeutic alternative(s). One commenter recommended that CMS identify no more than two comparators, one of which should be the lowest cost alternative and the other the most commonly used alternative. Another commenter stated that there is variability in how different entities define therapeutic categories, which results in different combinations of drugs in that therapeutic category. Many commenters recommended that CMS provide manufacturers, health care providers, and patients with the opportunity to participate in the selection of the therapeutic alternative(s).

Response: CMS appreciates commenters' feedback. As described in section 60.3.1 of this guidance, CMS will identify the therapeutic alternative(s) based on clinical appropriateness and consideration of various sources of evidence including clinical guidelines, peer-reviewed literature, drug compendia, and data submitted by manufacturers and the public, and not based on the cost of therapeutic alternative(s). CMS also may consult with FDA in the process of identifying other approved therapies for the same indication and with health care providers, patients or patient organizations, and academic experts to ensure that the appropriate therapeutic alternative(s) are selected. CMS expects that the negotiation offer/counteroffer exchange, as well as the negotiation meetings, will offer an opportunity for discussion about the therapeutic

alternative(s) with manufacturers. Further, as described in section 60.4 of this guidance, CMS will provide additional engagement opportunities for interested parties via manufacturer data submission-focused meetings and patient-focused listening sessions after the October 2, 2023 deadline for submission of information on the section 1194(e) data. CMS will provide additional information about these engagement opportunities at a later date.

Comment: Some commenters requested clarification as to whether generic drugs and biosimilars may be included as the therapeutic alternative(s). A few commenters opposed such inclusion because it would enable CMS to undervalue medicines. A few commenters expressed support for including generic and biosimilar therapeutic alternative(s) to establish the starting point for the initial offer.

Response: CMS appreciates commenters' feedback. As described in sections 60.3.1 and 60.3.2 of this guidance, CMS will consider the range of Part D net prices and/or ASPs of therapeutic alternative(s) for the selected drug, including prices of generic and biosimilar therapeutic alternative(s) if clinically appropriate.

Comment: Some commenters expressed support for CMS' proposal to consider the Part D net price or ASP of therapeutic alternative(s) for the selected drug as the starting point for the initial offer. A few commenters had concerns that considering Part D net prices would result in an inflated starting point and recommended CMS use the lowest net price or ASP as the starting point or the manufacturing cost and adjust based on clinical benefit. Another commenter recommended that CMS go beyond the net price of therapeutic alternative(s) to include all health system costs associated with the selected drug and its therapeutic alternative(s). One commenter recommended that if there are multiple therapeutic alternatives, CMS should use the highest-value alternative. Some commenters proposed additional options for the offer starting point, including using the MFP ceiling as the starting point or using comparative effectiveness to establish a price range or threshold for the initial offer.

Response: CMS understands concerns that using the Part D net price or ASP of a therapeutic alternative for the selected drug may result in a higher starting point; however, using net price(s) and ASP(s) of therapeutic alternative(s) enables CMS to start developing the initial offer within the context of the cost and clinical benefit of a group of drugs that treat the same disease or condition. As described in section 60.3.2 of this guidance, CMS will consider the range of Part D net prices and/or ASP(s) of therapeutic alternative(s), which may include consideration of generics and biosimilars as well as on- and off-label use (if such use is included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia). Some of the proposed alternatives for determining an offer starting point would not consider the clinical benefit provided by the selected drug relative to its therapeutic alternative(s). For example, if CMS were to use the MFP ceiling for the selected drug as the starting point, all adjustments to the starting point would be decreases, which could limit CMS' ability to adjust the starting point to recognize superior clinical benefit of the selected drug compared to therapeutic alternative(s). Rather than using manufacturing costs as a starting point, CMS will adjust the preliminary price based on manufacturer-specific data elements, including but not limited to the unit costs of production.

Comment: A couple of commenters indicated that CMS' intent to cap the offer starting point at the MFP ceiling is inconsistent with the statute. These commenters noted that the statute only requires that CMS not make an initial offer or accept a counteroffer that is above the statutory ceiling, and that limiting each step of the initial offer development process at the ceiling would lower the amount CMS could subsequently adjust based on other statutory factors (i.e., manufacturer-submitted data and clinical benefit).

Response: CMS appreciates commenters' feedback. CMS believes that the statute grants CMS flexibility to determine the amount of the initial offer, provided that the offer does not exceed the ceiling. Specifically, section 1194(b)(2)(F) of the Act requires that CMS may not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling, but does not prohibit CMS from applying the ceiling when determining the starting point of the initial offer. Further, section 1194(b)(1) of the Act instructs CMS to develop and use a consistent methodology and process for negotiations that aims to achieve agreement on the lowest MFP for each selected drug. CMS' approach of using the Part D net price or ASP of the therapeutic alternative(s), as applicable, as the starting point to determine the initial offer only if it is lower than the ceiling is consistent with this directive. As discussed in section 60.3 of this revised guidance, CMS will further adjust the starting point by the other factors specified in section 1194(e) of the Act.

Comment: CMS received many comments regarding its intent to use the Federal Supply Schedule (FSS) or Big Four price[16] as an offer starting point for selected drugs with no therapeutic alternative(s) or for selected drugs with therapeutic alternative(s) with Part D net prices and/or ASPs greater than the statutory ceiling. Some commenters disagreed with CMS' approach, noting that these prices do not reflect market prices because of certain required discounts. Other commenters were concerned that if Medicare uses these prices, it could put upward pressure on the FSS and Big Four prices, or manufacturers would be less willing to provide price concessions to the Big Four.

Response: CMS thanks these commenters for their remarks and understands the concerns raised. As discussed in section 60.3 of this revised guidance, CMS will use FSS/Big Four prices in situations where the selected drug has no therapeutic alternative(s) or the price of the therapeutic alternative(s) exceeds the ceiling. CMS believes use of FSS/Big Four prices is appropriate in these situations, as these prices are publicly available and are reflective of prices available to other federal payers.

Comment: A commenter requested that CMS limit downward adjustments related to prior Federal financial support to an amount proportional to the amount of prior Federal financial support as a share of total investment in research and development (R&D) in the selected drug.

Response: CMS appreciates these suggestions. As described in section 60.3.4 of this guidance, for each selected drug, CMS may consider each factor outlined in section 1194(e)(1) in isolation or in combination with other factors. With respect to prior Federal financial support specifically,

[16] The Big Four price is the maximum price a drug manufacturer is allowed to charge the "Big Four" federal agencies, which are the Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard. See section 8126 of title 38 of the U.S. Code. See: https://www.cbo.gov/publication/57007.

CMS will consider the extent to which the Primary Manufacturer benefited from such Federal financial support with respect to the selected drug. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

Comment: Many commenters indicated the definition of unmet medical need provided in section 60.3.3.1 of the initial memorandum was too narrow and should include situations where patients may not respond to or tolerate available treatments or disease burden remains significant. Some commenters suggested the definition should consider populations with disparities in outcomes or access. Some commenters proposed adopting the definition of unmet need from the FDA's expedited review programs. One commenter suggested looking to the National Comprehensive Cancer Network (NCCN) definition. A couple of commenters suggested looking to the framework used for New Technology Add-On Payments (NTAP). Many commenters recommended incorporating the patient perspective and/or broader societal or public health benefits when determining whether a selected drug fulfills an unmet medical need. A few commenters suggested reviewing unmet medical need across a product's lifecycle. A couple of commenters suggested reviewing unmet medical need at the time of FDA approval.

Response: CMS appreciates commenters' feedback and has reviewed the variety of definitions and frameworks suggested. After consideration of these comments, CMS revised the definition of unmet medical need to further align with section 1194(e)(2)(D) of the Act and FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" to include drugs that may have a therapeutic alternative but the existing alternative does not adequately address the condition or disease indicated (as described in section 60.3.3.1 of this revised guidance). Because the FDA guidance was issued in May 2014 and includes nonbinding recommendations, CMS will consider the guidance a reference and will consider any updates concerning unmet medical need that may be issued by FDA. CMS encourages patients and other interested parties to submit their perspective on how a selected drug meets an unmet medical need through the Negotiation Data Elements ICR submission and in the patient-focused listening sessions that will be held in Fall 2023, per revised section 60.4. More information on patient-focused listening sessions is forthcoming.

CMS also appreciates comments suggesting unmet medical need should be evaluated across a product's lifecycle. CMS will evaluate unmet medical need as of the time the section 1194(e)(2) data is submitted, which aligns with CMS' approach to reviewing manufacturer costs and data, therapeutic alternative(s), and other negotiation factors.

Comment: Many commenters supported using clinical benefit as the primary means for developing the initial offer. A few commenters stated CMS should deemphasize distribution costs when reviewing manufacturer-submitted data. A commenter suggested manufacturer-submitted data only be considered for selected drugs that provide fewer clinical benefits than the therapeutic alternative(s).

Response: CMS appreciates commenters' support for using clinical benefit to inform the initial offer. CMS is required to consider the factors described in section 1194(e) of the Act, as applicable to the selected drug, but there is flexibility to use these factors to inform the initial

offer and final offer, if applicable, in such a way as to recognize the unique characteristics of a selected drug. Regarding distribution costs, as described in section 60.3 of this guidance, CMS will adjust the starting point for the initial offer based on factors related to clinical benefit and then consider manufacturer-submitted data for additional adjustments, as appropriate. CMS also notes that the information submitted by the manufacturer and the public as well as information gathered through CMS' analysis will be considered in totality.

Comment: A few commenters suggested CMS should apply special considerations when evaluating orphan drugs or apply an upward adjustment for drugs with orphan indications, drugs that represent a significant therapeutic advance, and drugs that address an unmet medical need(s).

Response: As noted in the guidance, CMS will consider the totality of evidence when developing the initial offer. If a selected drug represents a significant therapeutic advance or addresses an unmet medical need, all other factors held constant, the initial offer for that selected drug would be higher than if this were not the case. CMS continues to explore whether there are additional actions that can be taken in the Negotiation Program to support orphan drug development, and CMS appreciates continued input from interested parties on this topic.

Comment: Many commenters requested additional detail on how negotiation factors, including those submitted by the Primary Manufacturer, would be weighted and how evidence would be evaluated and prioritized, stating additional transparency is needed. Many commenters suggested developing or adopting an existing framework for evaluating submitted information. A commenter requested CMS define "therapeutic advance."

Response: CMS appreciates commenters' feedback and recognizes the importance of balancing transparency and confidentiality in the negotiation process. CMS believes it is important to maintain flexibility when considering how each negotiation factor contributes to the initial offer and final offer, if applicable, which may be impacted by the unique characteristics of each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives. Regarding therapeutic advance, CMS will determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes for the selected drug compared to its therapeutic alternative(s) as described in section 60.3.3.1 of this revised guidance. CMS also included considerations for how evidence will be prioritized in section 50.2 of the initial memorandum and this revised guidance.

Comment: Many commenters recommended that real-world evidence,[17] information from clinical experts, and/or patient and caregiver perspectives be prioritized when reviewing negotiation factors. A few commenters suggested both qualitative and quantitative approaches be used to review negotiation factors and develop an initial offer. One commenter noted that CMS

[17] Real-world evidence is clinical evidence about the usage and potential health benefits or risks of a medical product derived from real-world data. Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. From *Framework for FDA's Real-World Evidence Program*, December 2018. See: https://www fda.gov/media/120060/download.

should consider the limitations of real-world evidence, particularly real-world evidence based on patient registry data and the limitations of data from electronic health records and billing records.

Response: CMS agrees with commenters on the importance of real-world evidence as well as the limitations of such evidence, as with any type of data. CMS also agrees with commenters on the importance of the perspective of clinicians, patients, and caregivers. CMS included real-world evidence and consultation with clinical experts and academic researchers in the initial memorandum and, as described in section 60.4 of this revised guidance, CMS will host patient-focused listening sessions that would be open to the public, including patients, beneficiaries, caregivers, consumer and patient advocacy organizations, and other interested parties, to share patient-focused input on therapeutic alternative(s) and other section 1194(e)(2) data regarding selected drugs. CMS may also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant health outcomes of the patient taking the selected drug. As noted in the initial and revised guidance, CMS will take a qualitative perspective when reviewing a selected drug and consider the evidence, including real-world evidence, clinical input, and patient and caregiver input, in totality. By employing a qualitative approach to information review rather than a more formulaic quantitative approach, CMS is able to preserve flexibility in negotiation, including the ability to consider nuanced differences between different drugs that might not be captured in a more thoroughly pre-specified quantitative approach.

Comment: A few commenters noted that CMS should include the caregiver experience and equity as factors in the negotiation process. A couple of commenters requested that for specific populations, CMS relax data prioritization standards to ensure underserved and underrepresented populations are considered. One commenter recommended that CMS prioritize studies that include individuals from diverse racial and ethnic backgrounds.

Response: CMS thanks these commenters for their feedback. Health equity is the first pillar of the CMS Strategic Plan, which builds health equity into the core functions of CMS, including the Negotiation Program.[18] As noted in the initial memorandum, CMS will consider information related to a selected drug within specific populations. In this revised guidance, CMS clarified that this includes underserved and underrepresented populations, as applicable, that may be experiencing disparities in health outcomes or access to the selected drug. As noted above, CMS will also consider the caregiver perspective to the extent that input reflects directly upon the experience or relevant health outcomes of the patient taking the selected drug. This information will be collected using the Negotiation Date Elements ICR and is open to the public. All applicable negotiation factors will be considered in totality for each selected drug.

Comment: Some commenters suggested that the negotiation factors be expanded to include adherence, convenience, societal impact, caregiver burden, independence, lost wages, travel expenses, costs to patients, medical costs, value of hope, cost of side effects, and other indirect costs. One commenter recommended that CMS de-prioritize or exclude indirect health benefits and instead focus solely on health outcomes to develop the initial offer.

Response: CMS agrees that factors such as adherence and convenience (as applicable to patient experience and outcomes) are important to consider for a selected drug. CMS views such factors

[18] See: https://www.cms.gov/cms-strategic-plan.

as directly related to patient experience and as such, considers these to be included in the factors outlined in the guidance. CMS appreciates commenters' suggestions to add broader societal, economic, and public health factors to those that will be considered during negotiation. Upon reviewing commenters' suggestions for additional factors, CMS revised the guidance to include consideration of both health outcomes and other outcomes when evaluating the benefit of the selected drug and therapeutic alternative(s). Outcomes such as changes to productivity, independence, and quality of life will be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug and are permitted in accordance with section 1194(e)(2).

Comment: Some commenters recommended using Multi-Criteria Decision Analysis (MCDA) as a framework for evaluating evidence related to a selected drug and its therapeutic alternative(s).

Response: CMS appreciates this suggestion. Due to the statutory timeline, conducting a full MCDA is not feasible. CMS will consider whether the general approach used in MCDA can serve as an informative framework for evaluating evidence.

Comment: A few commenters suggested that CMS share its literature review and other materials related to the selected drug and its therapeutic alternative(s) with the manufacturer of the selected drug.

Response: Per section 1194(b)(2) of the Act and this revised guidance, CMS will provide each manufacturer of a selected drug with an initial offer and a concise justification of the factors used to develop the offer.

Comment: Many commenters stated that CMS should not decrease the initial offer based on existing patents and exclusivities provided by the FD&C Act or PHS Act and recommended the initial offer be increased in cases where a drug has existing patents and exclusivities. Many commenters are concerned that a downward adjustment based on patents and exclusivities will stifle innovation, may impact patient access, disincentivize R&D, and work against the purpose of the patent system. A few commenters believe a downward adjustment based on patents and exclusivities exceeds CMS' statutory authority. A few commenters noted that CMS' action may constitute "a taking requiring just compensation" under the Fifth Amendment's Takings Clause and stated that patents are a constitutionally protected property right.

Response: CMS appreciates commenter feedback on adjusting the initial offer price based on patents and exclusivities provided by the FD&C Act or PHS Act ("exclusivities"). The statute explicitly directs CMS to consider data on approved patents and exclusivities in its determination of the amount of the initial offer. CMS does not believe that its implementation of this statutory mandate constitutes a taking or otherwise implicates or violates the Fifth Amendment Takings Clause. CMS also notes that the example provided in the initial memorandum was intended to provide an illustrative example of how such data could be considered in developing an initial offer. However, as discussed in section 60.3.4 of this revised guidance, following further consideration of the issue, CMS has omitted the example provided in the initial memorandum. This revised guidance clarifies CMS' belief that this information will support CMS' consideration of the 1194(e)(1) and 1194(e)(2) factors described in section 60 of this revised

guidance. For instance, patents and exclusivities may inform CMS' understanding of therapeutic alternatives and other available therapy for the purposes of adjusting for clinical benefit, including consideration of whether the selected drug represents a therapeutic advance or meets an unmet medical need. More specifically, in light of exclusivities, there may be no other available therapy aside from the selected drug that adequately addresses treatment or diagnosis of a condition; consideration of such information would be relevant to CMS' consideration of the extent to which the selected drug addresses an unmet medical need for that condition.

Comment: Many commenters requested that CMS develop additional opportunities for patient, caregiver, and clinician input throughout the negotiation process, particularly to provide input on therapeutic alternative(s) to the selected drug, patient-reported outcomes, health outcomes, whether the drug fulfills an unmet medical need, weighing evidence, and benefits and impacts of the selected drug. Many commenters requested a structured, standardized means for such input to be provided such as roundtables, an advisory or stakeholder panel, listening sessions, town halls, additional meetings, or creating a patient ombudsman to engage with interested parties. A few commenters pointed to FDA's Patient-Focused Drug Development program as one that CMS can adopt or model. Some commenters requested that patients be recognized in this revised guidance as subject matter experts. Some commenters requested that patients and clinical experts be included early and throughout the negotiation process to provide input on therapeutic alternative(s) and negotiation factors such as outcomes of importance and care preferences.

Response: CMS appreciates commenters' recommendation to incorporate additional opportunities for patient, caregiver, and clinician input. In this revised guidance, patients and caregivers have been added as interested parties with whom CMS may consult. CMS will host patient-focused listening sessions that will be open to the public, including patients, beneficiaries, caregivers, consumer and patient advocacy organizations, health care providers, and other interested parties to share patient-focused input on therapeutic alternative(s) and other data on the factors in section 1194(e)(2) for a selected drug and its therapeutic alternative(s). These patient-focused listening sessions will occur in Fall 2023 after the section 1194(e) data submission, which will give patients and other interested parties additional time to prepare their feedback. CMS may draw from the principles and strategies in FDA's "Patient-Focused Drug Development – Collecting Comprehensive and Representative Patient Input" guidance when facilitating patient-focused listening sessions. Additional information is forthcoming.

Negotiation Process (Section 60.4)

Comment: Some commenters suggested that interested parties should be allowed to submit new section 1194(e) data after the October 2, 2023 initial price applicability year 2026 deadline when there is good cause. Commenters also said that not allowing new data submission until the negotiation meetings could result in an inefficient process. One commenter also mentioned that some new data may be in formats that are not conducive to meetings, such as graphs and charts.

Response: CMS recognizes the interest of manufacturers to be involved early in the negotiation process beyond the section 1194(e) data submission due on October 2, 2023. CMS also recognizes the value of current and future patient and other interested parties' input in the negotiation process as well as throughout the implementation of the Negotiation Program. CMS

revised this guidance to allow for meetings after the section 1194(e) data submission deadline of October 2, 2023, where manufacturers can provide context for their submissions, and listening sessions where patients and interested parties can provide input as CMS begins reviewing data.

First, CMS would meet with the Primary Manufacturer of each selected drug once after the October 2, 2023 deadline so that the manufacturer has an opportunity to present its section 1194(e) data submission and share its perspective. These meetings will occur in Fall 2023. Primary Manufacturers may bring materials to facilitate discussion and CMS may request any materials presented afterwards. Primary Manufacturers are limited to sharing 50 pages (or a combination of pages, slides, and/or charts totaling 50 pages) of material, in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting, anticipating that these materials may contain cross-references to other material, particularly other material already submitted to CMS. This material is meant to provide context on the Primary Manufacturer's 1194(e)(1) submission and may also be used to share any new information regarding the section 1194(e)(2) data that has been identified following the October 2nd data submission.

Second, CMS will host patient-focused listening sessions for the selected drugs that would be open to the public, including patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs. Interested parties may also use these listening sessions to orally share new information regarding the section 1194(e)(2) data that has been identified since the October 2nd deadline. These patient-focused listening sessions will occur in Fall 2023 after the section 1194(e) data submission deadline, which will give patients and other interested parties additional time to prepare their input. Additional information about these listening sessions will be shared in the future.

Manufacturers are required to provide information on the non-FAMP and information required to carry out negotiation (i.e., the section 1194(e)(1) data), by October 2, 2023 for initial price applicability year 2026. CMS expects Primary Manufacturers to submit information that is complete and accurate by this deadline. Information shared during the Primary Manufacturer meetings described above and materials shared afterwards should only contextualize the Primary Manufacturer's October 2nd section 1194(e)(1) submission; new section 1194(e)(1) data will not be considered. But, as described above, new information on section 1194(e)(2) data will be considered. Similarly, patients, beneficiaries, caregivers, consumer and patient advocacy organizations, and other interested parties may provide contextual information on their October 2nd section 1194(e)(2) data submission and/or share new section 1194(e)(2) data.

Comment: Some commenters recommended that CMS should allow negotiation meetings to happen throughout the negotiation period (i.e., between the publication of the selected drug list through the conclusion of negotiations), and not just in the situation when a manufacturer's counteroffer is rejected. A few commenters suggested specific periods during the negotiation process where CMS should hold meetings with manufacturers of selected drugs, such as after drug selection and prior to the initial offer.

Response: In response to comments requesting the opportunity to provide additional section 1194(e) data submissions to inform CMS' initial offer and negotiations after October 2, 2023, concerns about the tight timeline for data submission, and recommendations to remove any meeting caps and allow meetings throughout the negotiation period, CMS has revised this guidance to allow for manufacturer meetings and patient-focused listening sessions after the October 2, 2023 deadline. CMS would hold one meeting with the Primary Manufacturer of each selected drug to allow the Primary Manufacturer to provide context for the section 1194(e) data submission as CMS reviews the submitted data and develops its initial offer. The patient-focused listening sessions will be open to patients, beneficiaries, caregivers, consumer and patient advocacy organizations, and other interested parties and will invite attendees to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs. Manufacturer meetings and patient-focused listening sessions will occur in Fall 2023. CMS will schedule the meeting with the Primary Manufacturer once the selected drug list is published, and more information will be forthcoming from CMS regarding the patient-focused listening sessions after the selected drug list is published.

Comment: Some commenters stated that limiting negotiation meetings to a maximum of three meetings is restrictive and recommend that CMS allow for more exchanges throughout the negotiation period. One commenter asked that CMS make the meetings more transparent through recorded minutes, records of attendees, and allow any interested party to participate.

Response: The timeline for the negotiations extends from February 1, 2024, the statutory deadline for CMS to make the initial offer on a selected drug to a manufacturer, to July 31, 2024, a total of six months. The statutory deadline for the conclusion of negotiations is August 1, 2024. Up to three negotiation meetings with the manufacturer can occur. During these meetings, the Primary Manufacturer may provide context on the section 1194(e) data submission and additional relevant input on CMS' initial offer and the Primary Manufacturer's counteroffer as CMS reviews data and develops its final offer. Additional meetings (i.e., more than the maximum of three) during the negotiation period after the Primary Manufacturer's counteroffer, if applicable, are not feasible due to time constraints.

As part of the public explanation of the MFP, CMS will publish redacted information on any negotiation meetings that occur if a Primary Manufacturer's counteroffer is rejected.

As mentioned in the responses to the comments directly above, CMS is adding one meeting for each manufacturer and listening sessions for other interested parties after the data submission deadline and before CMS' initial offer is made. These meetings will allow Primary Manufacturers and other interested parties to share their perspectives as CMS reviews data and develops initial offers.

Comment: A few commenters suggested that CMS provide justifications for counteroffer responses and not just initial offers.

Response: CMS thanks these commenters for their feedback. Section 1194(b)(2)(D) of the Act requires that CMS provide the manufacturer with a written response to the manufacturer's counteroffer. CMS believes that if CMS declines the Primary Manufacturer's counteroffer and

offers a meeting, the first meeting between CMS and the Primary Manufacturer will provide an opportunity for CMS to explain its rationale for not accepting the manufacturer's counteroffer.

Comment: Some commenters asked that CMS' justification of its initial offer be meaningful and explain how CMS arrived at the offer. Commenters mentioned that the justification should include sources CMS referenced, section 1194(e) data considered and how they were weighted, therapeutic alternatives considered, interested parties consulted, and benefits and impacts of the drugs considered. One commenter asked that CMS issue a template for the initial offer justification in the final guidance.

Response: CMS thanks these commenters for their feedback and will consider the suggestion to include the information listed in the comment above when developing initial offers and concise justifications for selected drugs. Section 1194(b)(2)(B) of the Act directs CMS to provide a "concise justification" to the Primary Manufacturer when the initial offer is made. CMS will include information that helps the Primary Manufacturer understand the range of evidence and other information submitted pursuant to section 1194(e) that CMS found compelling in developing its initial offer. Because this information will be shared with the Primary Manufacturer, CMS believes the concise justification will be meaningful and provide information that will enable the manufacturer to develop its counteroffer. CMS does not plan on issuing a template for the initial offer or the concise justification but will release redacted information regarding the initial offer with the MFP explanation no later than March 1, 2025.

Comment: One commenter suggested that CMS issue a confidential report to manufacturers alongside the initial offer and concise justification. This confidential report would make manufacturers aware of section 1194(e)(2) data submitted by other interested parties and allow manufacturers to use that information in counteroffers, if applicable, and in future data submissions.

Response: CMS understands that manufacturers may benefit from awareness of section 1194(e)(2) data submitted by other interested parties during the negotiation period and that all interested parties would value receiving access to this information ahead of data submission for initial price applicability year 2027. CMS revised this guidance to state that CMS will aim to share with the Primary Manufacturer of a selected drug the section 1194(e)(2) data received from other interested parties during the negotiation period when feasible. These data will be appropriately redacted and will not include proprietary information, protected health information (PHI) / personally identifiable information (PII), or information that is protected from disclosure under other applicable law. If an MFP is reached during the negotiation period, CMS will issue the public explanation of the MFP no later than March 1, 2025. As part of this public explanation, CMS will share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. This redacted information will not contain any proprietary data, as described in section 40.2.1 of this guidance, PHI / PII, or other information that is protected from disclosure under other applicable law. However, as described in section 40.2.1, if a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary and will not redact it in the public explanation.

Comment: A few commenters asked CMS to commit to responding to counteroffers within 30 days of receipt. Commenters also recommended CMS give manufacturers at least 30 days to review and comment on CMS' response to counteroffers and asked CMS to consider these comments before setting the MFP.

Response: Section 60.4.3 of this revised guidance reaffirms the statement from section 60.4.4 of the initial memorandum that CMS will provide a written response to the manufacturer's counteroffer, if applicable, no later than 30 days after the receipt of the manufacturer's counteroffer. CMS made minor revisions to section 60.4.3 to clarify that CMS will respond in writing no later than 30 days after receipt of a manufacturer's counteroffer regardless of the nature of the response.

CMS declines to revise the guidance to allow manufacturers 30 days to review and comment on CMS' response to counteroffers. If a manufacturer's counteroffer is rejected, negotiation meetings with the Primary Manufacturer and CMS will span from approximately April 1, 2024 to June 28, 2024. This period exceeds 30 days and will give Primary Manufacturers the opportunity to comment on CMS' response to the counteroffer in negotiation meetings.

If applicable, CMS will issue a "Notification of Final Maximum Fair Price Offer" no later than July 15, 2024, and require Primary Manufacturers to respond to this final offer by July 31, 2024. Although this turnaround is less than 30 days, it will come at the end of approximately six months of negotiations (February 2024-July 2024) where there will have been ample opportunity for the Primary Manufacturer to review the initial offer, respond in writing via a counteroffer, and consider the discussions that occurred within the context of up to three negotiation meetings, including any additional proposals for an MFP made by CMS.

Comment: A couple of commenters recommended CMS establish a definition for "meeting" and consider adopting a policy similar to the 2017 FDA guidance "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products: Guidance for Industry," which details meeting criteria and has definitions for different tiers of meetings.

Response: CMS thanks these commenters for their feedback. CMS has updated the description of meeting criteria in section 60.4.3 of this guidance to provide more information on the number of permitted attendees, length of each meeting, meeting scope, and meeting logistics. CMS believes that the meetings as part of the negotiation process under the Negotiation Program have a different purpose than FDA's formal meetings under the user fee agreements and therefore has taken a different approach when defining its meeting standards.

Comment: One commenter suggested CMS allow Secondary Manufacturers to participate in the negotiation process, including negotiation meetings.

Response: CMS thanks this commenter for this feedback. As described in section 60.4.3 of this memorandum, negotiation meetings would be attended solely by representatives of both the Primary Manufacturer and of CMS. CMS will defer to the Primary Manufacturer to identify its preferred representatives it plans to have attend any negotiation meetings.

Comment: One commenter stated that if CMS and a manufacturer engage in bona fide negotiations that result in no agreement, then the MFP should be set at the ceiling.

Response: CMS believes that this suggestion does not align with the statute. The statute envisions a period of negotiations that are expected to result in an agreement between the two parties on MFP by a certain date. The statute does not provide a "default" option if negotiations are not successful. This recommendation is inconsistent with the framework of the statute and would undermine the purpose of the Negotiation Program if manufacturers are assured the ceiling as long as they engage in good faith efforts to negotiate on an MFP.

Comment: One commenter suggested CMS consider issuing further guidance in the future on how data will be used in the negotiation process to determine MFP, as this may promote reaching agreements during negotiations.

Response: CMS will consider the totality of evidence throughout the negotiation period, including when developing the initial offer, reviewing a possible counteroffer, and participating in negotiation meetings when applicable. CMS will leverage the negotiation data described in section 50 to inform the methodology described in section 60.3 and the negotiation process described in section 60.4. Additional documents, such as the various ICRs associated with the Negotiation Program and this revised guidance, provide more detail related to the negotiation process and how data will be used.[19]

Application of the MFP Across Dosage Forms and Strengths (Section 60.5)

Comment: Some commenters indicated that CMS' methodology for calculating the MFP and applying it across dosage forms and strengths is overcomplicated, arbitrary, and inconsistent with the statute. Some commenters also opposed CMS' proposal to use a 30-day equivalent supply to apply the MFP across dosage forms and strengths. A few commenters expressed support for CMS' approach to applying the MFP across dosage forms and strengths, including to new NDAs, BLAs, and NDCs.

Response: CMS appreciates commenters' feedback. The statute requires a single price negotiation to agree upon an MFP for a selected drug, and contemplates that CMS will establish "procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug." As such, CMS will identify one MFP for a selected drug, which it will base on the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths.

Comment: Some commenters opposed CMS' proposed approach to apply the MFP across dosage forms and strengths by calculating a WAC ratio that represents the WAC of a given dosage form and strength compared to the WAC of the whole drug. A few commenters indicated

[19] For ICRs related to the Negotiation Program, see: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

that WAC is a flawed measure because it does not reflect discounts and that it changes over time. A couple of commenters recommended that CMS consider other price metrics such as AMP.

Response: CMS appreciates commenters' concerns regarding the use of the published WAC. For initial price applicability year 2026, CMS will use the WAC ratio to apply the MFP across dosage forms and strengths of a selected drug and will monitor changes to WAC relative to other pricing data, as well as shifts in utilization across dosage forms and strengths. CMS appreciates the commenters' recommendation to use AMP, but is concerned that using AMP prices in place of WAC could potentially disclose manufacturers' proprietary data. CMS recognizes there may be other ways to apply the MFP to dosage forms and strengths and will monitor whether this policy serves the intent of the Negotiation Program. As noted throughout this revised guidance, the policies described for the Negotiation Program are for initial price applicability year 2026, and CMS may consider additional policies for future years of the Negotiation Program.

Comment: Some commenters requested that for purposes of transparency and clarity, CMS provide to manufacturers the data used in MFP calculations, include example calculations in guidance, and publish a decision-making framework.

Response: CMS agrees with commenters about the importance of clarity and transparency in MFP calculations. CMS believes the discussion in sections 60.2 and 60.5 of this revised guidance sufficiently describes the methodologies CMS will use to calculate a single ceiling for a selected drug and to apply the single MFP negotiated for a selected drug across dosage forms and strengths of the selected drug (as identified at the NDC-11 level on the list of NDC-11s of the selected drug in the CMS HPMS, per section 40.2 of this revised guidance) and as such, this revised guidance does not include example calculations. However, as discussed in section 60.4 of this revised guidance, CMS will provide to the Primary Manufacturer information on the calculation of the statutorily-determined ceiling and application of a single MFP across dosage forms and strengths. However, CMS is not able to provide manufacturers with all data used in MFP calculations, as some of the calculations use proprietary pricing information.

Publication of the MFP (Section 60.6)

Comment: Some commenters recommended that the public explanation of the MFP provide details on the negotiation process, what data were considered, and how they were weighted when arriving at the final MFP. Commenters also suggested CMS share information on methodologies, therapeutic alternatives, outcomes metrics, interested parties engaged, and comparative effectiveness research considered. Several commenters also requested CMS explain how patient experience data and real-world evidence were used and how unmet need was factored in when developing the MFP. Commenters also broadly recommended that the public explanation of the MFP be transparent and detailed.

Response: CMS believes that all interested parties should have a transparent understanding of the process and rationale that CMS and the Primary Manufacturer of the selected drug used when negotiating the MFP and how that reasoning evolved over time. In addition to the data elements required by law to be submitted by the Primary Manufacturer regarding the selected drug, CMS expects robust participation by interested parties in submitting information and participating in

the patient-focused listening sessions for the selected drugs. As required under section 1195(a)(1) of the Act, CMS will publish the public explanation of the MFP for each selected drug no later than March 1, 2025. The public explanation, as described in the revised section 60.6.1 of this guidance, will include a narrative explanation of the negotiation process that occurred with that manufacturer and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable, in alignment with the confidentiality policy described in section 40.2. CMS will also strive to share the section 1194(e)(2) data submitted by the public with the Primary Manufacturer of a selected drug during the negotiation period. This data will be redacted as per the confidentiality standards described in section 40.2 and will not include proprietary information, PHI / PII, or other information that is protected from disclosure under other applicable law. CMS thanks these commenters for their feedback.

Comment: A few commenters recommended CMS make the publication of the MFP and explanation clear, accessible, and transparently available for the public. These comments mention ensuring the information is easy to read, easy to access, and developed in a consumer-friendly format. A couple of commenters suggested CMS include information on how beneficiaries can access the MFP and provide a process to follow if the MFP is not honored. One commenter suggested a webpage that provides the brand name (proprietary name) and generic name (non-proprietary name) for each selected drug where there is an MFP, MFPs for all dosage forms, and the dates the prices are in effect. Another commenter suggested providing a summary in the public explanation so that patients can understand the negotiation process and what to expect when procuring a medication with an MFP.

Response: CMS thanks these commenters for their feedback regarding the publication of the MFPs of the selected drugs and explanations of those MFPs. As described in section 60.6 of this revised guidance, CMS will publish the following on the CMS website by September 1, 2024 for all initial price applicability year 2026 selected drugs where an MFP was agreed upon: the selected drug, the initial price applicability year, and the MFP pricing file for that selected drug. The MFP file will contain the MFP as applied to each selected drug at the single MFP for a 30-day equivalent supply, NDC-9 per unit price, and NDC-11 per package price and will be updated annually to show the inflation-adjusted MFP for the selected drug. CMS will also publish on the CMS website: when a drug is no longer a selected drug and the reason for that change, and situations in which an MFP between a Primary Manufacturer and CMS is not agreed upon. No later than March 1, 2025, CMS will publish the public explanation of the MFP for each initial price applicability year 2026 selected drug. CMS is committed to providing accessible educational materials to beneficiaries, and the pharmacies, mail order services and other dispensers that serve them, about the MFPs for selected drugs and how they can report a violation if they do not believe that they were able to access the MFP for a selected drug.

Comment: Some commenters urged CMS to provide as much information as legally possible when issuing the public explanation of the MFP. These commenters stated that a high level of transparency will garner confidence that the negotiated MFP is the lowest price that CMS could obtain. One commenter asked that CMS release at minimum non-FAMP, R&D costs and recoupment, and unit costs of production, and distribution. Other commenters stated that the only

information that should be withheld from public explanations are R&D costs, unit costs of production, and certain net pricing information.

Response: CMS thanks these commenters for their feedback. CMS is committed to a negotiation process that is transparent and respects confidentiality of proprietary information. CMS appreciates the need to balance both transparency in the negotiation process to assure interested parties and the public that the negotiations were conducted in a fair manner, and that CMS attempted to achieve agreement on the lowest possible MFP for the selected price for Medicare beneficiaries, with the need to maintain the confidentiality of certain information, including manufacturers' proprietary data. As part of the public explanation of the MFP, CMS will release a narrative explanation of the negotiation process and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. All information that CMS publishes as part of the public explanation and any other public documents related to the MFP and negotiation process will abide by the confidentiality policy described in section 40.2 and redact proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law.

Comment: One commenter expressed concern that CMS' definition of R&D costs and recoupment was too narrow and suggested that CMS broaden its scope for R&D costs for failed and abandoned products to include all products in the relevant disease state, not just products with the same active moiety / active ingredient as the selected drug. The commenter also felt that CMS' intent to compare R&D costs and global, net revenue reported resulted in an unfair comparison, as global revenue may include products and indications without FDA approval and be supported by separate clinical trials. The commenter asked, if CMS does not revise the definitions, that CMS explain the calculation methodology and inputs in all publications regarding the negotiation process, especially the public explanation of the MFP. The commenter also said CMS should note where its definitions of concepts may differ from others.

Response: CMS thanks this commenter for this feedback. CMS believes that for the purpose of the Negotiation Program, the definition of R&D costs is sufficiently broad, as reflected in the additional revisions and clarifications made to Appendix C, as noted below. To the extent R&D costs and recoupment inform the final MFP for a selected drug, this information and how it was used will be described, with appropriate redactions for proprietary information, as part of the public explanation of the MFP. For more information on CMS' consideration of R&D costs and recoupment definitions, please see the comment and response section for Appendix C.

Comment: One commenter recommended that CMS carefully evaluate what information to include in the public explanation of the MFP and consider whether requests not to disclose some information are to protect business interests or to undermine a transparent process.

Response: CMS thanks the commenter for this feedback. CMS is committed to a transparent process and will follow the confidentiality policy as described in section 40.2 in this revised guidance when developing the public explanation of the MFP. As discussed earlier in this section, as part of the public explanation, CMS will publish redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS' publication of this information will abide by the confidentiality

policy described in section 40.2 and redact proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law.

Comment: One commenter suggested CMS limit its disclosure of information in the public explanation of the MFP to only information that is already public information.

Response: CMS thanks the commenter for this feedback. CMS is committed to a transparent process and will follow the confidentiality policy as described in section 40.2 in this revised guidance when developing the public explanation of the MFP.

Comment: Some commenters recommended that CMS allow manufacturers to review the explanation for the MFP before it is published so that manufacturers can provide comments and raise concerns about inadvertent disclosure of confidential information.

Response: CMS recognizes the interests of the manufacturers in making sure that certain data they provided to CMS for the negotiation process remain confidential. The statute does not require disclosure of the explanations of the MFP provided to manufacturers before the explanations are made public. Additionally, section 40.2 of this revised guidance describes the information from manufacturers that CMS will consider and maintain as confidential. CMS does not intend to share the explanations of the MFP with manufacturers before releasing the explanations to the public.

Comment: Many commenters suggested that CMS publish the explanation of MFP for all selected drugs with an MFP before the statutorily defined deadline for initial price applicability year 2026 of March 1, 2025. Some commenters recommended that CMS release the explanations along with the first set of MFPs for selected drugs on September 1, 2024, while other commenters did not specify a date. Commenters suggested an earlier publication so that interested parties can review the explanation and understand CMS' negotiation process ahead of submitting section 1194(e) data for initial price applicability year 2027 by the March 1, 2025 deadline.

Response: CMS thanks these commenters for their feedback. According to the statute, the public explanation of the MFP must be published no later than March 1, 2025 for initial price applicability year 2026 selected drugs. CMS understands commenters' interest in reviewing these public explanations in advance of the deadline for manufacturers of drugs selected for negotiation for initial price applicability year 2027 to submit their information, and will strive to release the public explanation of the MFP as soon as practicable. CMS notes that the policies for initial price applicability year 2027 will be shared in future guidance, including whether the policies adopted for section 1194(e)(2) submissions for initial price applicability year 2026 will apply in a similar manner for initial price applicability year 2027, and if so, when those submissions would be due.

Comment: One commenter recommended that, in addition to the public explanation of the MFP, CMS issue a summary report for all negotiated drugs in initial price applicability year 2026 and provide data on various negotiation outcomes. The commenter also suggested a summary report

and using SSR Health and IQVIA data may avoid confidentiality concerns around data from manufacturers.

Response: CMS thanks these commenters for their feedback. In response to comments, CMS revised section 60.6.1 of this guidance so that the public explanation of the MFP now includes a narrative explanation of the negotiation process and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS' publication of this information will abide by the confidentiality policy described in section 40.2 and redact any proprietary information, PHI / PII, and information that is protected from disclosure under other applicable law. CMS believes that, with these revisions, the public explanation of the MFP will be sufficiently comprehensive and will achieve the goals suggested by the commenter.

Comment: One commenter recommended that CMS publish the NDCs along with the list of MFPs for selected drugs. One commenter recommended that when CMS releases MFPs and associated data, the list should include selected drug active moieties / active ingredients, their respective NDCs, and unit-level MFPs in a structured and machine-readable format. The commenter also suggested CMS provide additional context on how CMS will use NDC-9s to calculate the unit-level MFPs for every dosage form and strength of the selected drug and how the structure and formatting of the MFP file release will be affected by FDA's proposed rule on the NDC-12 format.[20]

Response: CMS thanks the commenter for this recommendation. CMS will publish by September 1, 2024 the MFP for each drug selected for initial price applicability year 2026 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file (which will contain the MFP as applied to each selected drug at the single MFP for a 30-day equivalent supply, NDC-9 per unit price, and NDC-11 per package price and will be updated annually to show the inflation-adjusted MFP for the selected drug), and the explanation for the MFP (published at a later date). The MFP file will be machine-readable and in a .CSV format. While CMS understands FDA has issued a proposed rule regarding changes to the format of FDA-issued NDCs, CMS does not believe that this proposed rule is relevant to the Negotiation Program or the establishment of the MFP for initial price applicability year 2026 because the policy, if finalized as proposed, would take effect five years after the final rule is published.

Exclusion from the Negotiation Process Based on Generic or Biosimilar Availability (Section 60.7) and Establishment of MFPs After the Negotiation Deadline (Section 60.8)

CMS solicited comment on these sections, but did not receive any comments that are not otherwise addressed elsewhere (see the "Bona Fide Marketing" section below).

[20] Revising the National Drug Code Format and Drug Label Barcode Requirements, July 25, 2022, available at https://www.federalregister.gov/documents/2022/07/25/2022-15414/revising-the-national-drug-code-format-and-drug-label-barcode-requirements

Removal from the Selected Drug List (Section 70)

Comment: Some commenters recommended CMS not apply the MFP to a selected drug if CMS determines that a generic drug or biosimilar is approved and marketed after the negotiation period but before the start of initial price applicability year 2026. One commenter recommended that CMS replace a selected drug that is removed from the selected drug list. One commenter recommended that, if a generic drug or biosimilar competitor of a selected drug receives FDA approval or licensure before the end of the negotiation period, CMS should establish a grace period after the negotiation period ends (e.g., 30 days) for CMS to consider whether that generic or biosimilar has been bona fide marketed. One commenter asserted that section 1192(e) of the Act requires CMS to remove a selected drug from the selected drug list if a generic drug or biosimilar is approved and marketed before the start of the applicable initial price applicability year.

Response: CMS thanks these commenters for the recommendations. Section 1192(c), not section 1192(e) of the Act, governs the circumstances under which a selected drug would be removed from the selected drug list after the date that that list is published. Section 1192(c) of the Act requires a selected drug that is included on the selected drug list to remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines the statutory criteria in section 1192(c) are met unless CMS makes the determination before or during the negotiation period that a generic drug or biosimilar product for the selected drug is approved or licensed and is marketed. CMS interprets this requirement such that a drug included on the selected drug list published for initial price applicability year 2026 will remain a selected drug for initial price applicability year 2026 unless CMS determines on or before August 1, 2024 that a generic drug or biosimilar product for the selected drug has been approved for marketing by the FDA, and that bona fide marketing exists for the generic drug or biosimilar product. If CMS determines between August 2, 2024 through March 31, 2026 that bona fide marketing exists for the generic drug or biosimilar, the selected drug would cease to be a selected drug after 2026, and no MFP would apply for 2027.

MFP-Eligible Individuals (Section 80)

Comment: One commenter recommended CMS clarify whether an MFP-eligible individual that is enrolled in Part D can receive a selected drug at the MFP if it is paid under Part B. The commenter also requested clarification that the MFP must be made available to an individual with Part D coverage, even if they choose not to use their insurance. One commenter asked CMS to detail how it will ensure access to an MFP for individuals seeking to obtain a selected drug under Part B or Part C. A couple of commenters recommended that CMS clarify that the MFP for initial price applicability year 2026 only applies when the beneficiary receives a selected drug under Part D and that the MFP does not apply when the beneficiary is administered a selected drug under Part B. One commenter stated that the definition of MFP-eligible individual includes an individual enrolled in a Medicare Advantage (MA) Plan who is furnished or administered the selected drug for which payment may be made under Part B.

Response: CMS thanks these commenters for their recommendations. CMS has clarified in section 80 of the guidance that for initial price applicability year 2026, an MFP for a selected

drug must be provided to a Medicare beneficiary who uses their Part D plan (including an MA-PD plan under Medicare Part C or an Employer Group Waiver Plan, but not a plan that receives the Retiree Drug Subsidy) if Part D coverage is provided under such plan for such selected drug. For initial price applicability year 2026, the MFP is not required to be made available to a Medicare beneficiary who uses other sources of prescription drug coverage, prescription drug discount cards, or cash. CMS has made conforming changes throughout this revised guidance to clarify the scope of the requirement to provide access to the MFP for initial price applicability year 2026. For initial price applicability year 2026, CMS does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to MFP eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan.

Bona Fide Marketing (Sections 30.1, 60.7, 70, and 90.4)

Comment: Several commenters supported CMS' proposal to determine whether bona fide marketing exists for a generic or biosimilar to (1) determine whether a drug should be selected as a qualifying single source drug, (2) determine whether a selected drug should be deselected, and (3) monitor in cases where a drug is not selected or after it has been deselected to ensure that bona fide marketing is still occurring. These commenters agreed with this approach to ensure that the presence in the market of a generic drug means that there is meaningful competition. Other commenters said that such monitoring is warranted given manufacturers' past market behavior, and identified certain market-limiting agreements that some brand name manufacturers have entered into with generic drug manufacturers to limit the supply of the generic drug and thus inhibit competition. The commenters maintained that such arrangements justify CMS' proposal to determine whether bona fide marketing of a generic or biosimilar is actually occurring. Some commenters suggested that CMS require that manufacturers attest that they have not entered into any agreements that would limit the market share of the generic or biosimilar products, either implicitly or explicitly. One commenter also suggested that CMS require manufacturers submit all agreements provided to the Federal Trade Commission (FTC).

Response: CMS appreciates the support for its reading of the statute to contemplate a determination by the agency that a generic drug or biosimilar is being marketed on a bona fide basis as part of drug selection, deselection, and monitoring of the Negotiation Program. CMS agrees with these commenters that manufacturers' past behavior warrants CMS review on an ongoing basis as to whether a generic drug or biosimilar is being bona fide marketed. Absent this review, a generic drug or biosimilar manufacturer could launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the MFP should no longer apply. This result would be inconsistent with the text of the statute as well as its purpose, which is to lower drug prices for Medicare through either negotiation or price competition. Consistent with this statutory purpose, section 1192(e)(1) of the Act requires that a generic drug or biosimilar "is … marketed" in order for a drug or biological product to be excluded from the definition of a qualifying single source drug, and section 1192(c)(1) likewise requires that a generic or biosimilar "is marketed" in order for a selected drug to be deselected. This terminology demonstrates that Congress contemplated that a generic or biosimilar must have a continuing presence on the market in order to affect CMS' determination whether a drug should be selected as a qualifying single source drug or whether a

selected drug should be deselected. Manufacturers are welcome and encouraged to provide information to CMS about the market for generic drugs or biosimilars for the selected drug.

Comment: Many commenters stated CMS lacks statutory authority to define "marketed" for purposes of selected drug eligibility under the statute, including sections 1192(e)(1), 1192(e)(2)(B), and 1192(c) of the Act[21] differently from the first market date reported by the manufacturer to the Medicare Part D Drug Inflation Rebate Program. Further, these commenters stated that CMS lacks statutory authority to address "bona fide marketing" to implement the statutory requirement of determining if a generic or biosimilar is "approved and marketed" or "licensed and marketed" under sections 1192(c) and (e) of the Act. These commenters also asserted that CMS lacks statutory authority to review product utilization or assess "robust and meaningful competition" as part of a determination of whether a generic or biosimilar is "marketed." In addition, these commenters stated that "marketing" is already a term defined in the pharmaceutical industry, including by FDA and CMS, noting that in Appendix C of the initial memorandum, marketing is defined as the "introduction or delivery for introduction into interstate commerce of a drug product." These commenters stated that any review of "marketing" for purposes of drug selection under section 1192(e) of the Act or deselection under section 1192(c) of the Act must be based on the first "market date." One commenter stated that the IRA is not intended to review market performance across an arbitrary period of time but rather whether a generic or biosimilar is marketed at the point in time of CMS' determination of drug selection. Additionally, some commenters suggested that CMS lacks statutory authority to monitor marketing after a drug/biological is determined ineligible for selection or removed from the selected drug list.

Other commenters suggested that CMS clarify the term "bona fide marketing" and its application to the Biosimilar Delay special rule and drug selection and deselection.

Response: Section 1192 of the Act requires CMS to make a determination whether a generic drug or biosimilar "is marketed" in order to determine whether a listed drug / reference product should be selected as a qualifying single source drug or whether a selected drug should be deselected. Congress purposefully used different terminology in section 1192 than it did in section 1860D-14B of the Act, which established the new Medicare Part D Drug Inflation Rebate Program. In the latter provision, Congress referred to the date that a drug is "first marketed." The absence of similar terminology in section 1192 demonstrates that, for purposes of the Negotiation Program, Congress contemplated that a generic drug or biosimilar would have a continuing presence on the market in order to affect the status of a listed drug / reference product.

Consistent with the purpose of the statute to lower prices for Medicare through negotiation or price competition, the statute contemplates that, in making this determination, CMS would consider whether meaningful competition exists on an ongoing basis between a listed drug or

[21] These determinations include whether a drug/biologic is eligible as a qualifying single source drug under section 30.1 of this guidance and whether a selected drug should be removed under sections 60.7 and 70 of this guidance because either (1) the listed drug has an approved generic drug (under section 505(j) of the Federal Food, Drug, & Cosmetic Act) or (2) the reference product has a licensed biosimilar (under section 351(k) of the Public Health Service Act) that is marketed pursuant to that approval or license.

reference product and a generic drug or biosimilar. This determination requires more than solely token or de minimis availability of the products. For example, CMS is aware of situations in which a manufacturer of a brand name drug or biologic has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar, where the generic drug manufacturer agrees to limit production or distribution of the generic version of the drug, such that only a nominal quantity of product is allowed to enter the market. The result is a lack of meaningful price competition, and in that circumstance the generic drug or biosimilar is not "marketed" within the meaning of that term as it is used in the IRA.

Given the Negotiation Program is targeted at single source drugs and biologics that have been on the market for some time, for which no generic drug or biosimilar competition currently exists, the statutory directive would not be met if a qualifying single source drug were to avoid selection or be removed from the selected drug list where generic drug or biosimilar availability is limited by the Primary Manufacturer. It is consistent with the purpose of the statute to remove the MFP for a selected drug only when there is evidence that the selected drug or biological product is subject to meaningful competition. For example, Section 1192(e)(2)(A) of the statute provides that an "authorized generic" drug or biosimilar product "shall be treated as the same qualifying single source drug." Although an authorized generic may appear to be competing with the reference drug, authorized generics are typically marketed by the brand name drug company or another company with the brand company's permission, meaning that the relationship between the brand drug and its authorized generic is not meaningful competition in the way envisioned by Congress.

Whether such competition exists between a listed drug or reference product and a generic drug or biosimilar will depend on the totality of circumstances in existence at the time that CMS performs its function of making the determination whether a generic is being marketed. Accordingly, CMS maintains the approach in this guidance of determining if the manufacturer of the generic/biosimilar is engaged in bona fide marketing of the generic/biosimilar.

For a discussion of CMS' approach to the Biosimilar Delay rule, which under section 1192(f)(1)(A) requires CMS to make the statutory determination that there is a "high likelihood" that a biosimilar "will be licensed and marketed" within the relevant statutory time frame, see section 30.3.1 of this revised guidance.

Comment: Some commenters stated CMS lacks statutory authority to establish metrics of "sufficient quantities" and "market share" to assess bona fide marketing. These same commenters suggested these terms are vague and represent arbitrary requirements. A few commenters suggested specific thresholds that CMS could use to determine if meaningful competition exists. For example, one commenter suggested pulling a threshold from literature on competitive generic markets (which the commenter suggested is at least half of the market for small molecule drugs and at least 25 percent for biosimilars) and based on standardized prescriptions (e.g., a 30-day Part D supply) to estimate the generic drug penetration relative to the total volume of products dispensed in Medicare. Specifically, the commenter suggested the calculation of the number of standardized prescriptions dispensed for the generic product divided by the number of standardized prescriptions dispensed for the selected drug aggregated across all dosage forms and strengths, plus the number of standardized prescriptions dispensed for the

generic/biosimilar. Another commenter suggested a generic/biosimilar was effectively marketed when its market share is within a standard deviation of the mean for a given period of time since market entry and/or if its market share is at or above the mean of uptake at the point in time of CMS review regarding selection or deselection of the product.

One commenter requested CMS carefully consider what bar might be too high for a sufficient market share if certain factors of a market share are out of a manufacturer's control and limit competition, for example, this commenter said certain rebates can limit competitive entry.

Response: The statute requires CMS to determine whether a generic drug or biosimilar has been approved or licensed and is marketed pursuant to such approval or licensure for which the selected drug is the listed drug / reference product. Consistent with the purpose of the statute to lower prices for Medicare through negotiation or price competition, the statute contemplates that, in making this determination, CMS would consider whether meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar. This determination requires more than solely token or de minimis availability of the products. However, CMS agrees with the commenter than CMS will not set a single specific numeric threshold for meaningful generic drug or biosimilar competition for selected drugs because CMS does not believe there is one specified threshold that would appropriately capture meaningful competition in the market for every selected drug. As described below, CMS will review multiple data sources to inform its determination whether a generic drug or biosimilar is being marketed on a meaningful basis.

CMS clarified in this revised guidance that these data sources will be reviewed holistically to determine if meaningful competition exists in the market for purposes of: (1) the identification of qualifying single source drugs for initial price applicability year 2026 (see section 30.1), (2) removal from the selected drug list before or during negotiation or after an MFP is in effect (see section 70), and (3) monitoring whether a manufacturer of a generic or biosimilar is engaged in bona fide marketing of a drug/biologic determined ineligible as a qualifying single source drug as described in section 30.1 of this guidance or removed from selection as described in section 70 of this guidance because the selected drug was the listed drug or reference biologic for a generic or biosimilar (see section 90.4). Manufacturers can provide evidence to CMS regarding the market for an approved generic drug or biosimilar that references its drug(s) to inform CMS' monitoring for bona fide marketing after a drug is not selected or after deselection.

Comment: Some commenters expressed concern regarding the time difference between the actual date of marketing and the date of CMS' determination of bona fide marketing using PDE data because of the time lag for sales to be captured in PDE data. One commenter suggested that a 12-month review period is arbitrary and CMS failed to explain why this period was selected to establish if a generic/biosimilar is marketed. Another commenter stated that the initial six months of PDE data after market entry reflect a limited uptake because Part D plan sponsors add the drug to their formulary at the 180-day CMS deadline for Part D formulary inclusion, or not at all, and additionally there is a gradual transition for product uptake by providers and patients. Another commenter stated that CMS was relying on the indicator that shows slowest generic drug uptake by relying on PDE data.

Response: CMS thanks these commenters for their feedback regarding the timing of data review. CMS chose to review data over this 12-month time period for initial price applicability year 2026 because it believes that this time range will provide a sufficient window of opportunity to demonstrate whether a generic drug or biosimilar is marketed on a continuing basis while still allowing for sufficient time for that data to inform the selected drug list published on September 1, 2023 in accordance with section 1192(a) of the Act.

While CMS appreciates commenters' concerns regarding the time lag between a generic drug's availability and the ability to detect it in PDE data resulting from filled Part D prescriptions, CMS understands that generally this timing lag is relatively short as Part D plans are instructed to submit original PDEs to CMS within 30 days following the date the claim is received or date of service (whichever is greater)[22] and the average turnaround time to date of submission is fewer days.

Under Medicare Part D rules, 42 C.F.R. § 423.120(b)(5)(iv) permits immediate substitution of a generic drug for a brand name drug on a Part D formulary, and section 1860D-4(b)(3)(I)(ii) of the Act permits removal of a selected drug if permitted by § 423.120(b)(5)(iv) (or any successor regulation). CMS expects that Part D plans would immediately substitute a generic version of the selected drug for the brand version of the selected drug. In addition, Part D sponsors may add new generic drugs and biosimilars to their formularies at any time. Thus, the Part D rules allow for relatively quick formulary substitution of generic drugs for selected drugs and the addition of generic drug and biosimilar versions of selected drugs such that both should be evident in the PDE data relatively quickly.

Nonetheless, to address commenters' concerns about the implications of any lags in timing of data used and its implications on drug selection, CMS will also review AMP[23] data at the time of the initial qualifying single source drug determination under section 30.1 of this revised guidance, any subsequent removal from selection under sections 60.7 and 70 of this revised guidance, and when monitoring whether a manufacturer of a generic drug or biosimilar is engaged in bona fide marketing of a drug/biologic determined ineligible as a qualifying single source drug as described in section 30.1 of this guidance or removed from selection as described in section 70 of this guidance because the selected drug was the listed drug or reference biologic for a generic drug or biosimilar under section 90.4 of this revised guidance. AMP data may capture sales transactions in the supply chain in situations when use of the generic drugs in Part D plans has not yet become evident in the PDE data. A drug's AMP units (which represent manufacturer sales to retail pharmacies and wholesalers that distribute to retail community

[22] Timely Submission of Prescription Drug (PDE) Event Records and Resolution of Rejected PDEs, Centers for Medicare & Medicaid Services, October 6, 2011, available at: https://www.hhs.gov/guidance/document/revision-previous-guidance-titled-timely-submission-prescription-drug-event-pde-records.

[23] See definition at Section 1927(k)(1) of the Act. Average Manufacturer Price (AMP) is the average price paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturers. AMP was established under the Omnibus Budget Reconciliation Act of 1990 for the Medicaid Drug Rebate Program and is calculated using manufacturer sales transaction data, which include cash discounts, volume discounts, and other reductions in the actual price paid to the manufacturer. CMS receives AMP data from manufacturers that have an agreement with the Secretary of HHS as specified under Section 1927(a)(1) for all Medicaid-covered outpatient drugs on a monthly and quarterly basis, as well as data on the number of units sold by the manufacturer during those time periods.

pharmacies) are reported monthly to CMS as part of a manufacturer's reporting responsibilities under the Medicaid Drug Rebate Program. PDE data and AMP data will be reviewable once the generic drug is listed in the FDA Orange Book (using at least one dosage form and strength of the selected drug as the listed drug) or the biosimilar is listed in the FDA Purple Book (using at least one dosage form and strength of the selected drug as the reference product).

Comment: A few commenters requested CMS include other data sources in addition to PDE data, such as data from NADAC, IQVIA, and DailyMed data; determinations of national market share; presence at distributors and in group purchasing organization (GPO) contracts; and presence on formularies, to determine the presence of a marketed generic or biosimilar for the selection and/or deselection of a drug or biologic. One commenter requested that CMS permit manufacturers to certify the status of the marketing of generic drugs and biosimilars and determine this marketing status on an ongoing basis.

Response: CMS thanks these commenters for these suggestions of additional sources that may include useful information to demonstrate bona fide marketing of a generic drug or biosimilar. The determination whether a generic drug or biosimilar is being bona fide marketed on an ongoing basis is a totality-of-the-circumstances inquiry that will not necessarily turn on any one source of data. Manufacturers of selected drugs can provide evidence to CMS regarding the market for the generic drug or biosimilar versions of their selected drug(s) to inform CMS' monitoring for bona fide marketing before drug selections are made, or after deselection. In addition to also reviewing AMP data, given commenters' suggestions to include additional examples of such other data that may be used, CMS clarified in sections 70 and 90.4 of this guidance (with application to sections 30.1 and 60.7 by way of cross-reference to the discussion of bona fide marketing), that CMS will use multiple sources, including but not limited to, the examples as described in sections 70 and 90.4 of this revised guidance to determine if bona fide marketing exists of the generic drug or biosimilar under review. This monitoring will ensure that drugs and biologicals ineligible for selection or removed from selection are subject to competition from generic drugs and biologicals that are marketed on a meaningful basis. CMS retains the right to consider other data in monitoring if manufacturers of the applicable generic drug or biosimilar continue to engage in bona fide marketing once a selected drug is deselected.

Comment: A few commenters encouraged CMS to monitor for manufacturing and/or marketing arrangements that intend to limit generic competition. One commenter suggested that a drug or biologic should remain eligible as a selected drug, so long as the drug or biologic otherwise qualifies, in the presence of limited distribution agreements. Another commenter suggested CMS publish arrangements that CMS views as limiting competition as a component of monitoring bona fide marketing. A couple of commenters stated that monitoring of market competition is not within CMS' authority and cited FTC and FDA regulatory frameworks to address biosimilar and generic competition.

Response: CMS thanks these commenters for these suggestions. CMS believes that limited-distribution agreements can in fact limit the supply of an available generic drug. CMS reiterates that, for the purposes of the Negotiation Program, the statute instructs CMS to make a determination whether a generic drug or biosimilar "is marketed," which requires a determination whether the generic drug or biosimilar has a continuing presence on the market.

Congress used this language in furtherance of the purpose of the Negotiation Program, which is to lower costs for Medicare through negotiation or price competition. The statute accordingly contemplates that CMS' determination will turn on a finding whether meaningful market competition for such given generic drug or biosimilar biological product exists. While these market-limiting agreements may make CMS aware of a limitation on meaningful market competition, these agreements do not necessarily inform the agency whether such a limitation is manifesting itself in the marketplace. For this reason, CMS intends to monitor actual conditions in the marketplace through PDE and AMP data. However, as commenters suggest, CMS may consult with FTC to identify the types of agreements or arrangements that limit competition. FDA does not receive agreements of this type in the normal course of its operations.

Comment: One commenter asked what action might result if CMS determines through monitoring that a generic drug/biosimilar manufacturer is not engaging in bona fide marketing after CMS determined that there was an applicable generic drug/biosimilar for which the manufacturer was engaged in bona fide marketing.

Response: If the reason for disqualification as a qualifying single source drug is removed, the drug/biologic could be eligible for negotiation in a future price applicability year.

Comment: One commenter requested CMS evaluate whether its monitoring approach accurately captures true competition and whether any specific types of drug marketing/distribution agreements limit generic competition and include in this review the impact on payers, providers and insurers. A few commenters generally expressed concerns about potential impacts they suggested that the Negotiation Program might have on generic drug markets, which they suggested could broadly include reducing the impact to a manufacturer of being the first filer for generics, promoting pricing via negotiation in lieu of market competition, or deterring generic competition and increasing drug pricing costs to payers in certain drug market segments.

Response: CMS thanks these commenters for their input and will keep these comments in mind as CMS implements the Negotiation Program and monitors for bona fide marketing over time.

Monitoring Compliance and Civil Monetary Penalties (Sections 90.1 and 100)

Comment: Many commenters requested additional details regarding the scope and amount of the CMPs, detailed procedures for determining violations and imposing fines, and a review and appeal process for determinations of noncompliance prior to the imposition of CMPs and initiation of the procedures described in section 1128A of the Act. Additionally, some commenters suggested CMS undertake notice and comment rulemaking to provide the process steps and requirements of involved parties prior to imposing any CMPs, and a few commenters requested that CMS use a single notice and comment rulemaking process to capture all instances of CMP triggers under the IRA. A few commenters instructed CMS to look to examples of CMP application in other CMS programs, including Medicare Advantage and the HHS Office of the Inspector General (HHS OIG), when establishing its procedures for the Negotiation Program. A couple of commenters suggested that the dollar amount required by the IRA for a CMP requires rulemaking under the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution. A few commenters requested a delay in the implementation of CMPs until rulemaking occurs.

Response: CMS appreciates the concern for ensuring that administration of CMPs under section 1197 of the IRA and in accordance with the requirements of section 1128A of the Act is achieved via defined procedures, and appreciates the suggestions offered by commenters. In this revised guidance, CMS has provided additional information about compliance violations that may result in CMPs being issued; the notification process surrounding compliance violations, including reminders, warnings, Notices of Potential Noncompliance, and formal CMP Notifications; and has provided a series of informative example scenarios on the scope and calculation of CMPs when applicable. CMS has also added detail to the CMP Notification process, following the requirements of section 1128A of the Act. CMS directs commenters to section 100 of this guidance for additional information. CMS reviewed examples of CMP processes in other CMS programs to develop the procedures outlined in this guidance. The amounts of CMPs are defined in section 1197 of the IRA and will be applied accordingly. CMS defines the start date and end dates for calculating violations in section 100.2 of this revised guidance.

Sections 11001(c) and 11002(c) of the IRA provide that the Secretary "shall implement" the Negotiation Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." Thus, the initial memorandum is not subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute. Section 1197 of the Act indicates violations that warrant a CMP. This guidance is consistent with the statutory requirement to use program guidance to implement the Negotiation Program for 2026, 2027, and 2028 and to impose certain penalties for violations of the Negotiation Program.

Comment: Some commenters requested that CMS share information with the Primary Manufacturer in advance of the notice of imposition of a CMP and permit the Primary Manufacturer to cure the violation for which a CMP could be imposed. Some commenters also requested a reasonable time period be specified for this cure period and a process be provided to appeal a finding of noncompliance, including as a means to safeguard against a perceived or actual legal or factual error of CMS.

Response: CMS has added in this revised guidance additional details about how Primary Manufacturers will have an opportunity for corrective action in applicable circumstances. For example, CMS revised section 100.2 of this revised guidance to clarify that CMS may request additional information to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. In addition, CMS will issue a written reminder of the impending deadline for submission of information to include a warning of potential liability for a CMP upon failure to comply with the deadline.

Comment: A few commenters expressed support for the IRA's inclusion of CMPs to support the negotiation of the MFP.

Response: CMS thanks these commenters for their feedback.

Comment: Some commenters raised concerns regarding the application of CMPs to Primary Manufacturers due to the actions of a Secondary Manufacturer that does not provide data

required under section 1194(e)(1) of the Act or the action of other third parties, including pharmacies and providers, that do not provide access to the MFP for MFP-eligible individuals. A few commenters requested CMS limit the imposition of CMPs to only a Primary Manufacturers' actions, or alternatively, refrain from enforcement of the CMP on a Primary Manufacturer for a third party's actions in initial price applicability year 2026. One commenter suggested a Primary Manufacturer be able to raise a defense against a CMP when the violation at issue was committed by a Secondary Manufacturer. A few other commenters supported monitoring and imposition of CMPs on third parties via the Primary Manufacturer, and one commenter encouraged CMS to monitor Secondary Manufacturers directly.

Response: CMS appreciates commenters' feedback regarding the imposition of a CMP on the Primary Manufacturer based on the actions of a Secondary Manufacturer or other third party. Per section 40 of this revised guidance, a Secondary Manufacturer is defined as either (1) a manufacturer listed in an NDA or BLA for the selected drug or (2) an entity that has entered into an agreement with the Primary Manufacturer to market the selected drug. A Secondary Manufacturer will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meet these criteria. As such, a Primary Manufacturer may be required to request data from a Secondary Manufacturer including non-FAMP, current unit costs of production and distribution, and certain market data elements. As described in section 1193 of the Act (described in section 40 of this revised guidance) and included in the Manufacturer Agreement, the Primary Manufacturer is also responsible for ensuring access to the MFP for MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that dispense the selected drug to an MFP-eligible individual. Because CMS is entering into the Agreement with the Primary Manufacturer, it is the Primary Manufacturer that will be responsible for adhering to the terms of the Agreement. CMS believes the Primary Manufacturer, based on its arrangements with Secondary Manufacturer(s), can reasonably ensure that the Primary Manufacturer can comply with its Negotiation Program obligations with regards to data submission and ensuring the availability of the MFP for the selected drug sold by a Secondary Manufacturer(s). CMS is not aware of circumstances where a Secondary Manufacturer can operate without a formal arrangement of the Primary Manufacturer, through which the Primary Manufacturer can ensure compliance by the Secondary Manufacturer.

As is clarified in section 100 of this revised guidance, CMS will provide an opportunity for corrective action in certain instances of potential violation prior to imposing CMPs, which may provide Primary Manufacturers an opportunity to mitigate noncompliance related to Secondary Manufacturers in applicable situations.

Comment: One commenter requested CMS identify a pathway by which third parties could provide information regarding potential violations to CMS for investigation, while another commenter suggested an online form and toll-free phone number be established for consumer complaints on MFP availability.

Response: CMS appreciates commenters' feedback. CMS will establish a dedicated telephone line and/or e-mail inbox for interested parties to report any perceived MFP availability violations. Section 90.1 provides additional information regarding monitoring of manufacturer compliance. CMS anticipates providing more information on public monitoring in the future.

Comment: Several commenters requested CMS provide information about how CMS will interpret the term "knowingly" with regard to knowingly providing false information under section 100.3 of this guidance and as applicable to violations of the Agreement under section 100.2 of this guidance. Some commenters requested that CMS interpret "knowingly" based on a plain meaning of the term or uses by other CMS programs, OIG and the False Claims Act, while others requested CMS require "actual knowledge" of the act or omission.

Response: CMS appreciates these comments. After considering the comments received, CMS has adopted a standard for "knowingly" within the context of the Negotiation Program that conforms with the HHS OIG definition at 42 C.F.R. § 1003.110. Specifically, "knowingly" is interpreted to mean that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required. CMS adopts this standard for "knowingly" in section 100.3 of this revised guidance for purposes of whether a manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) of the Act for the Small Biotech Exception and whether any Biosimilar Manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Act for the Biosimilar Delay, as provided in section 1197(d) of the Act.

In applying CMPs, CMS intends to use discretion such that CMPs are reserved for instances of substantive noncompliance. These violations do not necessarily require the violation to be "knowing." Based on statutory requirements, CMS has clarified in section 100.2 that CMS maintains the authority to issue CMPs for substantive violations of the Agreement even in cases that violations are not "knowing."

Comment: Several commenters raised concerns that the detailed and numerous Primary Manufacturer data submission requirements under the Agreement will result in violations of compliance unintended by the Primary Manufacturer unless CMS allows for Primary Manufacturers to submit data based on a reasonable assumption of the IRA statutory data requirements.

Response: CMS appreciates commenters' feedback regarding the perceived potential for CMP liability based on unintended noncompliance with data submission requirements as set forth in section 1194(e)(1) and section 50 and Appendix C of the initial memorandum. As previously noted, CMS clarified in section 100 of this revised guidance that CMS will provide manufacturers with an opportunity, via the Notice of Potential Noncompliance, for corrective action in certain instances of potential violation prior to determining whether to impose a CMP. CMS has also provided responses regarding data submissions within the responses to Appendix C comments, including revisions to Appendix C definitions in response to commenters' requests for clarifications (e.g., unit type for non-FAMP, patents to be included). CMS also directs commenters to the 30-day notice for public comment on the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW), which incorporates revisions to instructions in response to comments CMS received in response to the 60-day notice for public comment. CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the Act or otherwise use reasonable

assumptions in lieu of the definitions in Appendix C of this revised guidance. Submitted data must align with the instructions in CMS' Negotiation Data Elements ICR and the definitions in Appendix C of this guidance to ensure that the data submitted by Primary Manufacturers are based on consistent definitions and scope.

Part D Formulary Inclusion of Selected Drugs (Section 110)

Comment: Many commenters expressed support for requiring selected drugs to be included on Part D formularies. Several other commenters noted that the IRA does not detail how selected drugs should be included on formularies; therefore, CMS should confirm plan formulary flexibilities for selected drugs. A few commenters also requested CMS clarify when the formulary inclusion requirement would not apply, such as when a selected drug is excluded from negotiation because of the introduction of a generic or biosimilar competitor. Additionally, a couple of commenters expressed concern that mandating inclusion of selected drugs on Part D formularies—without establishing guardrails to ensure beneficiary access—could create perverse incentives because plans could place selected drugs on less favorable tiers compared to non-selected drugs. Finally, a couple of commenters requested CMS clarify that it will not require that Part D formularies include every dosage form and strength of a selected drug, noting that plans could comply with the IRA if only one dosage form and strength of the selected drug is included. One commenter stated Congress did not intend that every dosage form and strength of a selected drug be included on formularies.

Response: CMS appreciates commenters' feedback and agrees with commenters about the importance of ensuring meaningful beneficiary access to selected drugs and their MFPs and ensuring that plans do not engage in gaming behavior. CMS shares concerns that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. CMS expects Part D sponsors to provide their enrollees with meaningful access to selected drugs and will use its comprehensive formulary review process to assess any practices that may undermine beneficiary access to selected drugs, as discussed in section 110 of this guidance. CMS maintains a robust, clinical formulary review process to ensure that all Part D plan formularies comply with statutory and regulatory requirements, including the requirement under section 1860D-11(e)(2)(D)(i) of the Act that CMS may only approve a Part D plan if it "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Further, if CMS identifies that Part D sponsors are not providing beneficiaries with meaningful access to selected drugs, CMS may consider implementing new requirements for future contract years. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs when clinically appropriate while allowing CMS to monitor practices that may undermine enrollee access to selected drugs and inform further action, as necessary.

Section 1860-D-4(b)(3)(I) of the Act requires Part D plan formularies to include each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP is in effect with respect to the year. Accordingly, all dosage forms and strengths of the selected drug that

constitute a covered Part D drug and for which the MFP is in effect must be included on formulary. In response to the comments requesting clarification on when the formulary inclusion requirement would cease to apply, CMS refers readers to section 70 of this revised guidance, which, in accordance with section 1192(c) of the Act, details when a selected drug will cease to be a selected drug because CMS determines that a generic or biosimilar competitor to the selected drug has been approved or licensed and marketed pursuant to such approval or licensure. CMS notes that, as specified by section 1860D-4(b)(3)(I)(ii) of the Act, nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under 42 C.F.R. § 423.120(b)(5)(iv) (or any successor regulation).

Comment: A couple of commenters stated CMS should require selected drugs to be placed on lower (preferred) formulary tiers, noting that this would reduce out-of-pocket costs for beneficiaries. A couple of commenters recommended CMS ensure parity between selected drugs and non-selected drugs, such as requiring plans to cover selected drugs on the most favorable tier as any brand name drug in the therapeutic class. One commenter stated CMS should require plans to place selected drugs on lower or equivalent tiers as their competitors. A few commenters indicated that selected drugs should be placed on formulary tiers with copayments rather than coinsurance to help beneficiaries plan for their drug expenses. One of these commenters added CMS should prohibit plans from placing selected drugs on tiers that require coinsurance. Finally, one commenter recommended CMS use the specialty tier cost threshold to determine tier placement of selected drugs. Specifically, selected drugs with monthly costs less than the specialty tier threshold could be placed on the lowest generic tier and selected drugs with monthly costs greater than the threshold could be placed on higher copayment tiers.

Response: CMS appreciates commenters' feedback. For contract year 2026, CMS is not implementing explicit tier placement requirements for selected drugs, but section 110 of this revised guidance indicates how CMS will use its formulary review process to assess potentially concerning review findings. CMS generally expects that Medicare beneficiaries taking selected drugs will benefit from the lower negotiated MFPs. While CMS understands that not all selected drugs and drug classes will present Part D sponsors and their Pharmacy & Therapeutics (P&T) Committees with the same formulary considerations and might not warrant the same formulary placement in all situations, CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs. To help ensure that beneficiaries have meaningful access to selected drugs and consistent with the agency's statutory obligation to monitor plan compliance with all applicable formulary requirements, CMS will use its formulary review process to assess any instances where Part D sponsors place selected drugs on non-preferred tiers or where a selected drug is placed on a higher tier than non-selected drugs in the same class. As discussed in section 110 of this revised guidance, as part of the annual bid review process, CMS will expect Part D sponsors to provide CMS with a reasonable justification to support the submitted plan design that includes any such practices. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). As CMS reviews Part D plan formularies to ensure they comply with statutory and regulatory

requirements, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, CMS will only approve a Part D plan bid submitted by a Part D plan sponsor if CMS does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs through tier placement in a clinically appropriate manner, while allowing CMS to monitor practices that may undermine beneficiary access to selected drugs and inform new requirements for future contract years.

Comment: Many commenters expressed concern that plans will use utilization management not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs that may be associated with higher rebates. Therefore, commenters suggested CMS should limit or prohibit utilization management for selected drugs. A few commenters asserted that maintaining the ability to use utilization management will best ensure that plans can negotiate effectively with interested parties to lower prescription drug costs.

Response: CMS appreciates commenters' feedback. For contract year 2026, CMS is not implementing explicit utilization management requirements for selected drugs, but section 110 of this revised guidance indicates how CMS will use its formulary review process to assess potentially concerning review findings. CMS shares the commenters' concerns that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. To help ensure that beneficiaries have meaningful access to selected drugs and consistent with the agency's statutory obligation to monitor plan compliance with all applicable utilization management requirements, CMS will use its formulary review process to assess any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy) or where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class. As discussed in section 110 of this guidance, as part of the annual bid review process, CMS will expect Part D sponsors to provide CMS with a reasonable justification to support the submitted plan design that includes any such practices. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS reviews all Part D plan formularies to ensure they comply with statutory and regulatory requirements and, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, will only approve a Part D plan bid submitted by a Part D plan sponsor if CMS does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. CMS believes this approach will provide Part D sponsors with the flexibility to continue to manage costs through utilization management in a clinically appropriate manner, while allowing CMS to monitor practices that may undermine beneficiary access to selected drugs and inform new requirements for future contract years.

Comment: Many commenters expressed concern that price negotiation, combined with changes in interested party liability from Part D redesign, will have significant impacts on the structure of Part D and could negatively impact patient access to medicines. These commenters recommended CMS monitor plan formularies and the extent to which plans are using utilization management and tiering for selected drugs. Some commenters also recommended CMS update rules and guidance around plan coverage decisions and create safeguards to ensure patient access to a selected drug.

Response: CMS thanks these commenters for sharing their concerns regarding patient access to selected drugs. CMS agrees with commenters about the importance of beneficiaries having meaningful access to selected drugs. As such, as discussed in section 110 of this guidance and consistent with the agency's statutory obligation to monitor plan compliance with all applicable formulary requirements, CMS will use its formulary review process to assess (1) any instances where Part D sponsors place selected drugs on non-preferred tiers, (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class, (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy), or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class. As CMS reviews Part D plan formularies to ensure they comply with statutory and regulatory requirements, pursuant to section 1860D-11(e)(2)(D)(i) of the Act, CMS will only approve a Part D plan if it does not find that the design of the plan and its benefits (including any formulary and tiered cost-sharing structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. While CMS is not implementing additional tier placement or utilization management requirements for selected drugs for contract year 2026, if CMS identifies that Part D sponsors are not providing beneficiaries with meaningful access to selected drugs, CMS may consider implementing new requirements for future contract years to ensure that Part D sponsors are not undermining beneficiary access to selected drugs.

Application of Medicare Part B and D Prescription Drug Inflation Rebate Programs to Selected Drugs (Section 120)

Comment: A few commenters stated that selected drugs should not be subject to inflation rebates. These commenters pointed to the Part B inflation rebate calculation in statute to assert that Congress did not intend for rebates to apply to selected drugs.

Response: The statute provides that the inflation rebates apply to selected drugs.[24] Specifically, the rebate calculation specified in section 1847A(i)(3)(A)(ii)(l) of the Act references section 1847A(b)(1)(B) of the Act, which includes payment for selected drugs. That is, there is no statutory exemption from inflation rebates for selected drugs. Note that CMS intends to issue final guidance relating to the Part B and Part D inflation rebates later in 2023.

Comment: Commenters requested clarification regarding the application of inflation rebates to selected drugs. One commenter asked CMS to clarify how MFPs will be factored into the inflation rebate calculations for selected drugs under the Part B and Part D programs. Another

[24] See sections 1847A(i) and 1860D-14B of the Act.

commenter urged CMS to issue guidance to ensure that the Negotiation Program and Part B Inflation Rebate Program do not have an interactive effect, and that inflation rebates should only apply when the manufacturer has increased its price.

Response: Section 120 of this guidance clarifies that the MFP for a selected drug is not included in the AMP for the selected drug and thus will not affect the Part D inflation rebate calculation.[25] CMS will provide additional information about how Part B inflation rebates apply to selected drugs in future guidance.

Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

Comment: Some commenters stated that the proposed framework for CMS' data collection and corresponding definitions to capture information required in sections 1194(e)(1) and (2) of the Act lacks the flexibility necessary to accommodate unique characteristics of different drugs/products that will be reviewed through the Negotiation Program. These commenters requested CMS rescind the proposed definitions and permit manufacturers to provide statutorily required data submissions based on reasonable assumptions along with a justification of such assumptions when interpreting the applicable IRA statutory requirements. Some commenters stated that because of the assumptions inherent in responding to a data request, CMS must use notice-and-comment rulemaking to provide information about required data. A few commenters raised concerns about differences between the definitions proposed in the initial memorandum and other pharmaceutical industry and/or government reporting requirements with related terms, and some commenters included specific term examples of these situations (included in other comments below). A couple of commenters expressed broad support for the definitions in Appendix C. Additionally, some commenters requested CMS allow manufacturers to provide supplemental data without text limits. Another commenter requested CMS establish a uniform starting point across data collections and not require data prior to this point because it could unfairly penalize manufacturers for previous pricing practices and data collection before the IRA went into effect.

Response: CMS thanks these commenters for articulating the considerations they will need to address when preparing to conform data submissions to the definitions provided in Appendix C of this guidance. CMS consulted with subject matter experts and federal agencies regarding the terms defined in this guidance. As already discussed herein, CMS engaged (and continues to engage) with interested parties through various platforms since passage of the IRA in August 2022. CMS has considered recommendations and suggestions in revising the definitions included in Appendix C of this guidance, which serve as the basis for the information to be collected under sections 1194(e)(1) and (2) of the Act. CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the Act or otherwise use reasonable assumptions. CMS believes it is important that data submissions reflect the application of consistent standards and definitions to permit appropriate consideration of such data, timely execution of the negotiation process, and enforcement actions, as warranted. As such, data submitted in response to this revised guidance must be based on consistent definitions and scope, as reflected in Appendix C of this revised guidance. CMS appreciates the resources required to meet these submission requirements. On

[25] See section 1927(k)(1)(B)(i)(VI) of the Act.

March 21, 2023, CMS released the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW) to detail the specific data that CMS is requesting for purposes of implementing the negotiation process to determine the MFP. The comment period in response to the 60-day notice closed on May 22, 2023. CMS is releasing a revised version of the Negotiation Data Elements ICR on June 30, 2023, and the 30-day comment period will close on July 31, 2023. The revised ICR is available here: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847. Comments must be submitted through www.regulations.gov.

Additionally, as explained in response to comments received regarding CMS' statutory authority to issue program instruction, sections 11001(c) and 11002(c) of the IRA state that CMS "shall implement" the Negotiation Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance"; thus, this revised guidance and corresponding data collection requirements are not subject to the notice-and-comment requirements of the Administrative Procedure Act or the Medicare statute. However, CMS is following requirements pursuant to the Paperwork Reduction Act of 1995 for information collection requests related to the administration of the Negotiation Program.

Comment: A few commenters asked for clarification on the requested data elements related to R&D costs. Some commenters expressed concern that CMS' definition of R&D costs is too narrow and excludes relevant costs such as those related to acquisition, ongoing studies or monitoring of a drug, and costs related to investments in technology that may apply to multiple drugs. One commenter recommended CMS exclude from the definition of R&D costs post-marketing clinical trials that were not completed and limit consideration of spending on abandoned and failed projects to those that were conducted within a narrower timeframe. One commenter expressed concern that the 8.1 percent capital rate specified in the guidance is too low. A few commenters stated CMS' approach for calculating recoupment of R&D costs by comparing global net lifetime revenue for the selected drug with R&D costs attributable to FDA-approved indications of the selected drug is imprecise or flawed and disadvantages the manufacturer.

Response: CMS thanks these commenters for their feedback. After consideration of the comments on this guidance and the Negotiation Data Elements ICR, CMS has revised Appendix C to consolidate several R&D cost categories. Specifically, as revised, the category "Post-Investigational New Drug (IND) Application Costs" includes costs for completed, FDA-required post-marketing trials, which were previously in their own category. The category "All Other R&D Direct Costs" includes costs associated with post-marketing trials that were not completed or were conducted for the purposes of marketing claims, which were previously in their own category. In addition, CMS revised the guidance to require reporting of acquisition costs as part of R&D costs rather than market data and revenue and sales volume data. CMS also revised the definition of basic pre-clinical research costs to clarify that the relevant time period for reporting such costs begins on the later of the date of initial discovery or the date the Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug. This revision was made to clarify that CMS does not expect the Primary Manufacturer to submit R&D costs for the time period prior to its acquisition of the rights to the selected drug.

Acknowledging that not all costs are mutually exclusive among products and that manufacturer investments can include failed drug candidates, CMS believes that for the purpose of the Negotiation Program, the definition of R&D costs is sufficiently broad. As required in section 1194(e)(1)(A), CMS must consider R&D "costs of the manufacturer related to the [selected] drug." Expanding the definition of such costs to include failures of products with different active moieties / active ingredients or mechanisms of action or in different therapeutic classes or other non-specific innovation-related costs goes beyond considering costs related to the R&D of the selected drug and does not provide a clear accounting of drug-specific R&D expenditures. In defining R&D costs, CMS considered a multitude of sources including government reports, literature searches, the FDA website, and discussions with experts. The definition is intended to be sufficiently broad to accommodate differences in accounting policies and cost allocations across different manufacturers. Manufacturers should submit additional R&D costs not included in other R&D definitions as part of "All Other R&D Direct Costs", as applicable. The 8.1 percent capital rate is consistent with assumptions used by the Congressional Budget Office in an April 2021 study on R&D in the pharmaceutical industry.[26]

CMS appreciates commenters sharing their concerns regarding comparisons of global, lifetime net revenue for the selected drug with R&D costs attributable to FDA-approved indications of the selected drug. CMS understands that R&D occurs globally and, as stated in the Negotiation Data Elements ICR instructions, the Primary Manufacturer must report R&D costs incurred in other countries that are related to the FDA-approved indication of a selected drug. As noted in the ICR and Appendix C of this revised guidance, R&D costs exclude costs associated with applying for and receiving foreign regulatory approvals. In response to commenters' concerns, CMS has revised Appendix C of this guidance, as well as the ICR, to clarify that CMS will consider both a Primary Manufacturer's global and also U.S. revenue when determining whether to adjust the preliminary price based on manufacturer-submitted data. Further, to align reporting of U.S. revenue with global total lifetime net revenue, CMS has (1) eliminated reporting of quarterly gross U.S. revenue and (2) replaced reporting of quarterly net revenue for the selected drug with U.S. lifetime net revenue for the selected drug.

Comment: Some commenters recommended CMS remove federal tax credits from the definition of prior Federal financial support and limit consideration of prior Federal financial support to only products with a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government agency. One commenter recommended that prior Federal financial support exclude indirect federal funding (e.g., provision of funding to a third party which then provides funding to the manufacturer). One commenter suggested including tax credits provided under the Orphan Drug Act and similar subsidies in addition to grants and contracts. Another commenter recommended CMS use broad definitions for "preclinical" and "novel discovery" to capture prior Federal financial support that occurs before a manufacturer acquires a viable drug product.

Response: CMS thanks these commenters for their feedback. CMS disagrees that tax credits should be excluded from the definition of prior Federal financial support. The federal government supports drug research through tax incentives. The statute does not require that CMS

[26] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," April 2021, available at https://www.cbo.gov/publication/57126.

only consider direct expenditures in prior Federal financial support or only government interest patents. CMS believes that the definition of prior Federal financial support appropriately captures industry and/or government standards in a manner that is consistent with the statutory requirements to use such information.

Comment: Several commenters raised concerns about challenges with obtaining requested information about current unit costs of production and distribution at the drug-specific level, which they stated is inconsistent with reporting requirements of other governmental bodies such as the SEC. One commenter recommended CMS allow manufacturers to use reasonable assumptions based on existing audited financial reports submitted to the SEC and/or generally accepted accounting principles. One commenter noted that it may not be able to obtain some of these data from Secondary Manufacturers. One commenter recommended CMS include channel fees in its definition of distribution costs. Several commenters recommended CMS allow manufacturers discretion to include production and distribution costs that are available to them and provide a narrative rationale for any factors they are not able to include.

Response: CMS appreciates commenters' concerns and feedback. In response to comments, CMS revised Appendix C to note that costs should be determined and reported in accordance with generally accepted accounting principles. CMS believes the Primary Manufacturer, based on its arrangements with Secondary Manufacturer(s), can reasonably ensure that the Primary Manufacturer can comply with its negotiation program obligations with regarding to data submission and ensuring the availability of MFP for selected drug sold by Secondary Manufacturer(s). CMS notes that because the agreement is between CMS and the Primary Manufacturer, it is the Primary Manufacturer's responsibility to submit certain data that will serve as the basis for offers and counteroffers. CMS declines to explicitly include channel fees in its definition of costs of distribution and notes that the definition generally refers to all (direct and allocation of indirect) costs related to packaging, labeling, and shipping operating costs for facilities and transportation. CMS refers commenters to the Negotiation Data Elements ICR for information about submitting explanations of various calculations, including unit production and distribution costs. Finally, CMS notes that the definitions of unit costs of production and distribution are intended to be sufficiently broad to account for various costs associated with producing and distributing drugs or biological products.

Comment: One commenter noted that manufacturers define kits differently than the National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards that are referenced in Appendix C. This commenter recommended including the definition to avoid confusion.

Response: This revised guidance includes a footnote to provide clarification with respect to the definition of kits to be clear that CMS is adopting the NCPDP definition for kits.

Comment: Some commenters disagreed with the scope of patent and exclusivity information that CMS proposed to collect and recommended CMS clarify and narrow the scope of these reporting requirements to, for example, include only U.S. patents and applications directly related to the Primary Manufacturer and/or selected drug. Some commenters also disagreed with the patent-related definitions adopted by CMS. A few commenters requested clarity with respect to certain terms used in this section, including the meaning of patents "linked to" or "relating to"

the selected drug. One commenter recommended removing required reporting of reference product exclusivity for biologics, stating that FDA only makes this determination if there is a regulatory necessity (as opposed to at the time of approval). A few commenters also recommended CMS obtain information about approved patent applications and marketing applications from FDA resources such as the Orange Book and Purple Book and that manufacturers be allowed to reference those sources in their submissions to CMS to reduce burden. One commenter recommended CMS align its terminology and standards with other federal laws and regulations such as those of FDA.

Response: CMS thanks these commenters for their suggestions. In drafting the Patents, Exclusivities, and Approvals section of Appendix C and the Negotiation Data Elements ICR, CMS consulted with the United States Patent and Trademark Office (USPTO) and reviewed the FD&C Act and FDA regulations. After consideration of the comments, CMS has revised Appendix C of this guidance to remove certain definitions and provide additional information about the types of patents and patent applications that CMS considers to be "related to" the selected drug. While CMS understands that certain patent information is submitted to other agencies and is publicly available in the FDA Orange and Purple Books, section 1194(e)(1)(D) of the Act requires that manufacturers submit patent information to CMS. Although some of the requested data may be publicly available, CMS may not be able to ensure that such data are complete or up-to-date. Further, other information required by section 1194(e)(1)(D) of the Act, for example, information about pending patent applications, may not be publicly available. CMS understands that FDA has not made a determination of first licensure for each 351(a) biological product included in the Purple Book and that the absence of a date of first licensure in the Purple Book does not mean that a biological product on the list is not, or was not, eligible for the periods of exclusivity described under the PHS Act. CMS expects that the Primary Manufacturer will report any periods of reference product exclusivity for the selected drug to the extent the determination of exclusivity is listed in the Purple Book.

Comment: A few commenters raised concerns that CMS' definitions in the Market Data Revenue and Sales Volume Data section were too broad and burdensome given the timeframe to collect data from all Secondary Manufacturers. Some commenters opposed CMS' intent to collect certain metrics such as "U.S. commercial average net unit price" and "manufacturer average net unit price to Part D plan sponsors." A few commenters requested CMS withdraw or clarify these metrics. Some commenters also were concerned with CMS requesting data on patient assistance, noting that patient assistance is not a form of price concession or remuneration. One commenter requested CMS remove all reporting of patient assistance or, minimally, clarify that patient assistance programs are defined as charitable free drug programs. One commenter noted the definitions included vague timeframes, which could lead to data discrepancies, and recommended CMS consider including firm dates in definitions. For example, the commenter suggested clarifying "quarterly total U.S. unit volume" and providing a specific quarter on which to report, including which specific quarter in the past five years. One commenter stated that the information collected pursuant to the definitions are considered confidential and proprietary information.

Response: CMS appreciates commenters' concerns. The statute requires CMS to broadly consider market data and revenue and sales data. As noted in guidance, CMS considers these

data to include WAC, Medicaid best price, AMP, FSS price, Big Four price, and U.S. commercial average net unit price, among other data. Data related to these definitions will be considered, in part, as the basis for offers and counteroffers. CMS clarified in Appendix C that patient assistance programs include manufacturer-run patient assistance programs that provide financial assistance such as coupons or copayment assistance or free drug products. In response to comments, CMS removed the metrics "manufacturer average net unit price to Part D plan sponsors" and "quarterly total U.S. unit volume." CMS removed "manufacturer average net unit price to Part D plan sponsors" because CMS does not plan to consider this information for the purposes of developing the initial offer. CMS removed "quarterly total U.S. volume" because CMS collects this information in other questions in the Negotiation Data Elements ICR (CMS-10847 / OMB 0938-NEW). CMS refers interested parties to the revised version of the Negotiation Data Elements ICR that is open for a 30-day public comment period through July 31, 2023. With respect to the comment about confidential and proprietary information, proprietary information, including trade secrets and confidential commercial or financial information, CMS will protect the confidentiality of any proprietary information from Primary Manufacturers or Secondary Manufacturers (described in section 40.2.1) as required under section 1193(c) of the Act and other applicable law.

Timeline for Medicare Drug Price Negotiation Program Initial Price Applicability Year 2026

Date	Milestone
June 30, 2023	Revised Negotiation Program guidance is published by CMS.
July 3, 2023	Latest date to submit Small Biotech Exception request to CMS for initial price applicability year 2026.
September 1, 2023*	CMS publishes list of up to 10 selected drugs for initial price applicability year 2026 of the Negotiation Program.
October 1, 2023*	Latest date for manufacturers of selected drugs to enter into a Medicare Drug Price Negotiation Program Agreement with CMS. Manufacturers of selected drugs without an Agreement in place are referred to IRS.
October 2, 2023*	Manufacturers' section 1194(e)(1) data submissions due to CMS. All voluntary submissions of section 1194(e)(2) data are also due on this date.
Fall 2023	CMS meets with the manufacturer of each selected drug to review data submissions, subject to manufacturer's interest in such meeting.
Fall 2023	CMS holds listening sessions with patients, consumer groups, and other interested parties to obtain input on selected drugs.
February 1, 2024*	Latest date for CMS initial offers to manufacturers for selected drugs, including concise justification of the initial offer.
March 2, 2024*	Latest date for counteroffers from manufacturers, if applicable, assuming initial offer sent to manufacturer by CMS on February 1, 2024.
April 1, 2024	Latest date for CMS to act on manufacturer counteroffer, assuming counteroffer is received by CMS on March 2, 2024. CMS may accept or decline such counteroffer.
April 1, 2024	Latest date for first CMS-manufacturer negotiation meeting to be scheduled if CMS declines the counteroffer, assuming initial offer was sent by CMS on February 1, 2024.

~April 1, 2024 through June 28, 2024	Up to three possible negotiation meetings between the manufacturer and CMS to negotiate MFP for the selected drug. Meetings can begin in late March or April depending on when CMS declines the counteroffer, if applicable, and scheduling.
July 15, 2024	Latest date for final CMS MFP offers to manufacturers if MFP not agreed to during negotiations.
July 31, 2024	Manufacturer response due to CMS regarding final CMS MFP offer.
August 1, 2024*	End of negotiation period for initial price applicability year 2026. Manufacturers of selected drugs without an MFP in place are referred to IRS.
September 1, 2024*	MFPs published for up to 10 selected drugs for 2026 for which MFP agreement has been reached with the manufacturer. CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, and the MFP file (which would be updated annually to show the inflation-adjusted MFP for a selected drug).
March 1, 2025*	CMS publishes explanation of MFP for each selected drug for which MFP agreement has been reached with the manufacturer. CMS will also release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable.
January 1, 2026*	MFPs for the selected drugs for which MFP agreement has been reached with the manufacturer go into effect.

*Denotes statutory dates

D. Revised Guidance on Medicare Prescription Drug Negotiation Program

10. Introduction

The purpose of this revised guidance is to provide interested parties with information regarding CMS' implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA) (P.L. 117-169), signed into law on August 16, 2022, which establish the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") to negotiate maximum fair prices (MFPs)[27] for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter "the Act") as added by sections 11001 and 11002 of the IRA.

Sections 11001(c) and 11002(c) of the IRA direct the Secretary of the Department of Health and Human Services (hereafter "the Secretary") to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, the Centers for Medicare & Medicaid Services (CMS) is issuing this revised guidance for implementation of the Negotiation Program for initial price applicability year 2026.

[27] In accordance with section 1191(c)(3) of the Social Security Act, maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

This revised guidance is not subject to the notice-and-comment requirements of the Administrative Procedure Act ("APA") or the Medicare statute, due to the requirement in sections 11001(c) and 11002(c) of the IRA to implement the Negotiation Program for 2026, 2027, and 2028 by program instruction or other forms of program guidance. The terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. The statutory directive in sections 11001(c) and 11002(c) thus specifies that CMS shall follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under the APA or the Medicare statute. Congress underscored this directive by placing the Negotiation Program in the newly-enacted Part E of Title XI of the Social Security Act.

Moreover, as explained in the initial memorandum, to the extent that this revised guidance establishes or changes any substantive legal standard, CMS found that notice and public procedure on this revised guidance would be impracticable, unnecessary, and contrary to the public interest in light of the statutory requirement to implement the Negotiation Program for 2026 by program instruction and in light of the complexity of the preparation that must be undertaken in advance of the publication by September 1, 2023 of the selected drug list for initial price applicability year 2026. In particular, manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture might be included on the selected drug list for initial price applicability year 2026. For example, manufacturers may need to engage in internal discussions regarding whether the manufacturer would choose to participate in the Negotiation Program if its drug is included among the selected drug list published on September 1, 2023, review the template Medicare Drug Price Negotiation Program Agreement and guidance to understand Negotiation Program requirements for participating manufacturers in advance of the statutory deadline for entering agreements of October 1, 2023, and gather information for potential submission to CMS by the statutory deadline of October 2, 2023. In addition, for the reasons explained below, the deadline for a biosimilar manufacturer to submit a delay request under section 1192(f) was May 22, 2023. CMS could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far in advance of these statutory deadlines to allow them adequate time to complete their preparations for participation in the Negotiation Program. Thus, CMS concluded that there was good cause to issue certain specified parts of the initial memorandum as final (i.e., section 30) without public comment and without a delayed effective date. Although CMS has endeavored to solicit public comment and to respond to comments to the extent that it would be feasible to do so consistent with the statutory deadlines for implementation of the Negotiation Program, CMS also concludes that there is good cause to issue this revised guidance as final without the 60-day period for public comment under the Medicare statute, and without a delayed effective date, in order to meet the statutory deadlines of the Negotiation Program and consistent with the authority provided to CMS in sections 11001(c) and 11002(c) of the IRA. *See* 5 U.S.C. § 553(b)(B) & (d)(3); *see also* section 1871(b)(2)(C) of the Act.

In this revised guidance, CMS has made clarifications and changes to the policies described in the initial memorandum in response to comments and based on CMS' further consideration of the relevant issues, including policies on which CMS did not expressly solicit comment.

This revised guidance describes how CMS will implement the Negotiation Program for initial price applicability year 2026 (January 1, 2026 to December 31, 2026), and specifies the requirements that will be applicable to manufacturers of drugs that are selected for negotiation and the procedures that may be applicable to drug manufacturers, Medicare Part D plans (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) Plans), pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D.

If any provision in this revised guidance is held to be invalid or unenforceable, it shall be severable from the remainder of this revised guidance, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances.

The table of contents for this revised guidance is as follows:

- Section 10 – Introduction
- Section 20 – Overview
- Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2026
  - 30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2026
    - 30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs
    - 30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs
    - 30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs
  - 30.2 Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2026
    - 30.2.1 Exception for Small Biotech Drugs
  - 30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026
    - 30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry
      - 30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026
      - 30.3.1.2 High Likelihood
      - 30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026
      - 30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026
  - 30.4 Publication of the Selected Drugs List
- Section 40 – Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026
  - 40.1 Entrance into an Agreement with CMS and Alternatives
  - 40.2 Submission of Manufacturer Data to Inform Negotiation
    - 40.2.1 Confidentiality of Proprietary Information
    - 40.2.2 Data and Information Use Provisions and Limitations
    - 40.2.3 Opportunity for Corrective Action Following Information Submission

- 40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years
- 40.4 Providing Access to the MFP
  - 40.4.1 Nonduplication with 340B Ceiling Price
- 40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program
- 40.6 Termination of the Agreement
- 40.7 Other Provisions in the Agreement

- Section 50 – Negotiation Factors
  - 50.1 Manufacturer-Specific Data
    - 50.1.1 Non-FAMP Data
  - 50.2 Evidence About Therapeutic Alternatives for the Selected Drug
- Section 60 – Negotiation Process
  - 60.1 Establishment of a Single MFP for Negotiation Purposes
  - 60.2 Limitations on Offer Amount
    - 60.2.1 Determination of the Ceiling for the MFP
    - 60.2.2 Sum of the Plan-Specific Enrollment Weighted Amounts
    - 60.2.3 Average Non-Federal Average Manufacturer Price
    - 60.2.4 Selection and Application of the Ceiling for the MFP
  - 60.3 Methodology for Developing an Initial Offer
    - 60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication
    - 60.3.2 Developing a Starting Point for the Initial Offer
    - 60.3.3 Adjusting the Starting Point Based on Clinical Benefit
      - 60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)
      - 60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives
      - 60.3.3.3 Preliminary Price
    - 60.3.4 Adjusting the Preliminary Price Based on Consideration of Manufacturer-Specific Data
  - 60.4 Negotiation Process
    - 60.4.1 Provision of an Initial Offer and Justification
    - 60.4.2 Required Components of a Counteroffer
    - 60.4.3 Negotiation Process After Manufacturer Counteroffer
    - 60.4.4 Determination that Negotiations Have Finished
  - 60.5 Application of the MFP Across Dosage Forms and Strengths
    - 60.5.1 Application of the MFP to New NDAs / BLAs or NDCs
  - 60.6 Publication of the MFP
    - 60.6.1 Explanation for the MFP
  - 60.7 Exclusion from the Negotiation Process Based on Generic or Biosimilar Availability
  - 60.8 Establishment of MFPs After the Negotiation Deadline
- Section 70 – Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect
- Section 80 – MFP-Eligible Individuals
- Section 90 – Manufacturer Compliance and Oversight

- 90.1 Monitoring of Manufacturer Compliance
- 90.2 Monitoring of Access to the MFP
- 90.3 26 U.S.C. Section 5000D Excise Tax on Sale of Designated Drugs
- 90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

- Section 100 – Civil Monetary Penalties
  - 100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP
  - 100.2 Violations of the Agreement
  - 100.3 Provision of False Information Related to the Small Biotech Exception and the Biosimilar Delay Rule
  - 100.4 Notice and Appeal Procedures
- Section 110 – Part D Formulary Inclusion of Selected Drugs
- Section 120 – Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs
- Appendix A – Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026
- Appendix B – Template for the Initial Delay Request Form
- Appendix C – Definitions for Purposes of Collecting Manufacturer-Specific Data

20. Overview

In accordance with sections 11001 and 11002 of the IRA, which created Part E under Title XI of the Act (sections 1191 through 1198), the Secretary is required to establish the Negotiation Program to negotiate MFPs for certain high expenditure, single source Medicare drugs. With respect to each initial price applicability year, CMS shall (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate and, if applicable, renegotiate MFPs for such selected drugs, in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) impose civil monetary penalties (CMPs) in accordance with section 1197 of the Act. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

As noted above, in order to facilitate the timely implementation of the Negotiation Program, CMS issued section 30 of the initial memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception Information Collection Request (ICR),[28] as discussed in section 30.2.1 of this revised guidance). To allow for public input, CMS voluntarily solicited comments on all other sections of the initial memorandum except for section 90.3 (which states that the Treasury Department will issue guidance relating to the excise tax in the coming weeks), and specifically on certain topics in the initial memorandum, including:

- Terms and conditions contained in the manufacturer agreement, including the manufacturer's and CMS' responsibilities (included in section 40 of this revised guidance);

[28] This ICR was approved on May 26, 2023. Small Biotech Exception (CMS-10844; OMB Control No. 1938-1443).

- Approach for considering (1) the manufacturer-reported data elements and (2) evidence about alternative treatments (included in section 60 of this revised guidance);
- Process for the offer and counteroffer exchange between CMS and manufacturers (included in section 60 of this revised guidance);
- Content of an explanation for the MFP (included in section 60 of this revised guidance);
- Method for applying the MFP across different dosage forms and strengths of a selected drug (included in section 60 of this revised guidance);
- Dispute resolution process for specific issues that are not exempt from administrative and judicial review under section 1198 (included in section 40.5 of this revised guidance); and
- Processes for compliance monitoring and imposition of CMPs for violations (included in sections 90 and 100 of this revised guidance).

In this revised guidance, CMS has made clarifications and changes in response to comments and based on CMS' further consideration of the relevant issues, including policies on which CMS did not expressly solicit comment.

30. Identification of Selected Drugs for Initial Price Applicability Year 2026

In order to facilitate the timely implementation of the Negotiation Program in accordance with statutory deadlines, CMS issued section 30 of the initial memorandum as final, without a comment solicitation (with the exception of the Small Biotech Exception ICR, as described in section 30.2.1 of this revised guidance). While CMS did not solicit comment in response to section 30, CMS did receive many thoughtful comments, and based on these comments and further consideration of the relevant issues, CMS identified certain policies where revisions to clarify the policy described in the initial memorandum would facilitate the implementation of the Negotiation Program for initial price applicability year 2026. CMS has noted in section 30, and in the summary of key changes and clarifications, where clarifying revisions were made.

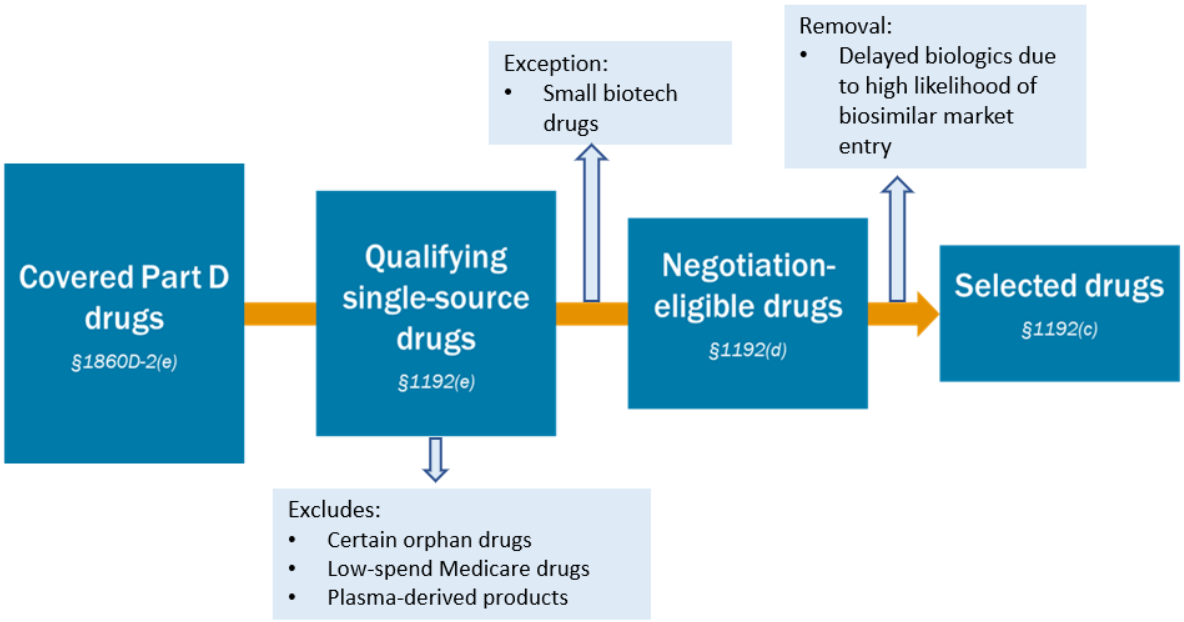
Section 1192 of the Act establishes the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs for an initial price applicability year. First, CMS will identify qualifying single source drugs in accordance with section 1192(e) of the Act, as described in section 30.1 of this revised guidance. CMS will exclude certain drugs in accordance with section 1192(e)(3) of the Act. Next, in accordance with section 1192(d) of the Act, using Total Expenditures[29] under Part D of Title XVIII for these qualifying single source drugs calculated using Part D prescription drug event (PDE) data for dates of service between June 1, 2022, and May 31, 2023, and other information described below, CMS will identify negotiation-eligible drugs for initial price applicability year

[29] For the purposes of the Negotiation Program, Total Expenditures under Part D of Title XVIII are defined in section 1191(c)(5) as total gross covered prescription drug costs (as defined in section 1860D-15(b)(3)). The term "gross covered prescription drug costs" is also defined in the Part D regulations at 42 C.F.R. § 423.308. In the initial memorandum, CMS indicated that it had proposed to update this regulatory definition of gross covered prescription drug costs to eliminate any potential ambiguity in the regulation text and help to ensure there is a consistent understanding of the term for purposes of both the Part D program and the IRA. Since the initial memorandum was issued, CMS has issued a final rule adopting the proposed revisions to 42 C.F.R. § 423.308. (See Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Final Rule (0938-AU96), 88 Fed. Reg. 22,120, 22,259 (Apr. 12, 2023)).

2026 as described in section 30.2 of this revised guidance (in this step, CMS will also exclude certain drugs in accordance with section 1192(d)(2) and (3) of the Act).

In accordance with section 1192(d)(1) of the Act, CMS will rank negotiation-eligible drugs for initial price applicability year 2026 according to the Total Expenditures for such drugs under Part D of Title XVIII for the 12-month period described above (described in section 30.3 of this revised guidance). In accordance with section 1192(a) of the Act and subject to the Special Rule to delay the selection and negotiation of biologics for biosimilar market entry described in section 1192(f) of the Act, CMS will select the 10 negotiation-eligible drugs with the highest Total Expenditures under Part D of Title XVIII for negotiation for initial price applicability year 2026 (described in section 30.3 of this revised guidance) and publish a list of those ten selected drugs not later than September 1, 2023 (described in section 30.4 of this revised guidance). Figure 1 provides a visual depiction of this process, and detailed guidance pertaining to this process for initial price applicability year 2026 is included below.

Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2026



30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2026

For initial price applicability year 2026, in accordance with section 1192(e)(1) of the Act, CMS will define a qualifying single source drug as a covered Part D drug (as defined in section 1860D-2(e) of the Act) that meets the following criteria:

- For drug products, a qualifying single source drug is a drug (1) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the

date of such approval; and (3) that is not the listed drug for any drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act.

- For biological products, a qualifying single source drug is a biological product (1) that is licensed under section 351(a) of the Public Health Service Act (PHS Act) and marketed pursuant to such licensure; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 11 years have elapsed since the date of such licensure; and (3) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act.

Section 1192(d)(3)(B) of the Act states that CMS shall use data that are aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or package type of the drug for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug under section 1192(d)(1) of the Act and applying the exception for small biotech drugs under section 1192(d)(2) of the Act. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures "to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug."

Identifying potential qualifying single source drugs:
In accordance with the statutory language cited above, for purposes of the Negotiation Program, CMS will identify a potential qualifying single source drug[30] using:

- For drug products, all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA)[31], inclusive of products that are marketed pursuant to different NDAs. The potential qualifying single source drug will also include all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such NDA(s), (2) authorized generic drugs that are marketed pursuant to such NDA(s), and (3) multi-market approval (MMA) products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s);
- For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA),[32] inclusive of products that are marketed pursuant to different BLAs. The potential qualifying single source drug will also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s) described in the prior sentence that are: (1) repackaged and relabeled products that are marketed pursuant to such BLA(s), (2) authorized biologic products that are marketed pursuant to such BLA(s), and (3) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such BLA(s).

[30] Throughout this revised guidance, a qualifying single source drug means the specific constituent dosage forms and strengths (at the NDC-9 or NDC-11 level) that are identified as aggregated under the NDA(s) / BLA(s) for the active moiety / active ingredient as outlined in section 30.1 of this revised guidance.
[31] As described in section 505(c) of the FD&C Act.
[32] As described in section 351(a) of the PHS Act.

As an example, entity A holds three NDAs for drug products with the same active moiety approved in NDA-1, NDA-2, and NDA-3. Entity A manufactures and markets three different strengths as an immediate release tablet pursuant to NDA-1, three different strengths as an extended-release tablet pursuant to NDA-2, and three different strengths as a subcutaneous injectable pursuant to NDA-3. Additionally, under an agreement with entity A, entity B repackages three strengths of the immediate release tablets manufactured by entity A and markets them pursuant to NDA-1. In this scenario, all 12 of these drug products, including the repackaged products, will be aggregated as a single potential qualifying single source drug for purposes of identifying negotiation-eligible drugs.

This approach to identifying a potential qualifying single source drug aligns with the requirement in section 1192(d)(3)(B) of the Act to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. Consistent with this statutory instruction, this approach is also appropriate because CMS is aware that new dosage forms or different routes of administration of the same active moiety / active ingredient have been submitted by the same NDA / BLA holder and approved under different NDAs or BLAs.

Section 1192(e)(2)(A) of the Act states that an authorized generic drug and the qualifying single source drug that is the listed drug or reference product of that authorized generic drug shall be treated as the same qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act as (1) in the case of a drug product, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act), and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act[33] and is marketed, sold, or distributed, directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark.

If a drug is a fixed combination drug[34] with two or more active moieties / active ingredients, the distinct combination of active moieties / active ingredients will be considered as one active moiety / active ingredient for the purpose of identifying qualifying single source drugs. Therefore, all formulations of this distinct combination offered by the same NDA / BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties / active ingredients that is offered by the same NDA / BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate potential qualifying single source drug. For example, a long-acting corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA / BLA holder that contains the same corticosteroid combined with a long-acting beta agonist. In this example, the long-acting corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

[33] CMS is interpreting the reference to "licensed under section 351(a) of such Act" to mean licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.
[34] For purposes of the Negotiation Program, the term "fixed combination drug" has the meaning specified in 21 C.F.R. § 300.50.

Applying statutory criteria for qualifying single source drugs:
In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, at least 7 years (for drug products) or 11 years (for biological products) must have elapsed between the U.S. Food and Drug Administration (FDA) date of approval or licensure, as applicable, and the selected drug publication date. To determine the date of approval or licensure for a potential qualifying single source drug with more than one FDA application number, CMS will use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA / BLA holder for the active moiety / active ingredient, or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients. The selected drug publication date for initial price applicability year 2026 is September 1, 2023, as specified in section 1191(d)(1) of the Act. As such, for initial price applicability year 2026, the initial approval for a drug product to be considered a qualifying single source drug must have been on or before September 1, 2016, and the date of initial licensure for a biological product to be considered a qualifying single source drug must have been on or before September 1, 2012.

For example, if 12 years had elapsed between the original approval for NDA-1 cited in the previous example above and September 1, 2023, then the potential qualifying single source drug defined above would meet this statutory criterion for qualifying single source drugs (even if less than seven years had elapsed between the approval dates for NDA-2 or NDA-3 and September 1, 2023), consistent with the statutory directives in section 1192(d)(3)(B) of the Act to aggregate data across dosage forms and strengths of the drug, including new formulations of the drug.

In accordance with section 1192(e)(1) of the Act, to be considered a qualifying single source drug, a product cannot be the listed drug for any drug approved and marketed under an ANDA under section 505(j) of the FD&C Act, and a biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act. CMS will use FDA reference sources, including the Orange Book[35] and Purple Book,[36] to determine whether a generic drug or biosimilar biological product has been approved or licensed for any of the strengths or dosage forms of the potential qualifying single source drugs for initial price applicability year 2026.

In accordance with section 1192(c) and (e) of the Act for the purpose of identifying qualifying single source drugs for initial price applicability year 2026, CMS is clarifying in this revised guidance that it will review PDE data for the 12-month period beginning August 16, 2022 and ending August 15, 2023, using PDE data available on August 16, 2023, as well as Average Manufacturer Price (AMP)[37] data for the 12-month period beginning August 1, 2022 and ending July 31, 2023, using the AMP data available on August 16, 2023, for a given generic drug or biosimilar biological product for which a potential qualifying single source drug is the listed drug or reference product. The determination whether a generic drug or biosimilar is marketed on a bona fide basis will be a holistic inquiry, but these sources of data over the specified intervals

[35] See: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.
[36] See: https://purplebooksearch.fda.gov/.
[37] Average Manufacturer Price means, with respect to a covered outpatient drug of a manufacturer for a rebate period (calendar quarter), the average price paid to the manufacturer for the drug in the United States by: (i) wholesalers for drugs distributed to retail community pharmacies; and, (ii) retail community pharmacies that purchase drugs directly from the manufacturer, subject to certain exclusions. See section 1927(k)(1) of the Act.

will be informative for that determination. CMS will consider a generic drug or biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of that drug or product is engaging in bona fide marketing of that drug or product (see section 70 of this revised guidance for additional details). CMS has chosen these time periods to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published by September 1, 2023 in accordance with section 1192(a) of the Act.

If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic or biosimilar biological products that CMS determines are approved and marketed based on the process described in this revised guidance, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026. If CMS determines that the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026 because a manufacturer of such generic drug or biosimilar biological product has engaged in bona fide marketing of the generic drug or biosimilar biological product, CMS will monitor to ensure continued bona fide marketing of the generic drug or biosimilar biological product based on the approach described in section 90.4 of this revised guidance.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(A) of the Act, CMS will exclude certain orphan drugs when identifying qualifying single source drugs ("the Orphan Drug Exclusion"). Specifically, CMS will exclude a drug or biological product that is designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and for which the only approved indication (or indications) is for such disease or condition. To be considered for the Orphan Drug Exclusion, the drug or biological product must (1) be designated as a drug for only one rare disease or condition under section 526 of the FD&C Act and (2) be approved by the FDA only for one or more indications within such designated rare disease or condition. CMS is clarifying in this revised guidance that a drug that has orphan designations for more than one rare disease or condition will not qualify for the Orphan Drug Exclusion, even if the drug has not been approved for any indications for the additional rare disease(s) or condition(s). CMS further clarifies that it will consider only active designations and active approvals when evaluating a drug for the Orphan Drug Exclusion; that is, CMS will not consider withdrawn orphan designations or withdrawn approvals as disqualifying a drug from the Orphan Drug Exclusion.

In order to qualify for the Orphan Drug Exclusion, all dosage forms and strengths of the qualifying single source drug described in section 30.1 of this revised guidance must meet the criteria for exclusion. CMS will use the FDA Orphan Drug Product designation database[38] and approvals on the FDA website[39] to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the Orphan Drug Exclusion. CMS will also consult with FDA as needed, including to determine whether a drug is designated for, or approved for indications for, one or more rare disease(s) or condition(s). In this revised guidance, CMS is clarifying that, in the event that a drug or biological product loses Orphan Drug Exclusion status,

[38] See: https://www.accessdata.fda.gov/scripts/opdlisting/oopd/.
[39] See: https://www.accessdata.fda.gov/scripts/cder/daf/.

pursuant to sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act, CMS will use the date of the earliest approval or licensure of the drug or biological product (as described above in section 30.1) to determine whether the product is a qualifying single source drug that may be selected for negotiation if it meets all other Negotiation Program eligibility criteria, regardless of whether the drug or biological product previously qualified for an exclusion under section 1192(e)(3)(A) of the Act.

As noted in the initial memorandum, CMS is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development, and CMS appreciates continued input from interested parties on this topic. Additional information about how CMS will consider the impact of a selected drug (and its therapeutic alternative(s)) on specific populations as well as the extent to which the selected drug (and its therapeutic alternative(s)) meets an unmet medical need in CMS' development of an initial offer is in section 60.3.3 of this revised guidance.

30.1.2 Low-Spend Medicare Drug Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(B) of the Act, CMS will also exclude low-spend Medicare drugs or biological products with less than $200,000,000 in combined expenditures under Medicare Parts B and D when identifying qualifying single source drugs ("the Low-Spend Medicare Drug Exclusion"). For initial price applicability year 2026, CMS will identify low-spend Medicare drugs as follows:

- CMS will identify PDE data combined with Part B claims data for each potential qualifying single source drug for dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. To allow a reasonable amount of time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been submitted no later than 30 days[40] after May 31, 2023, i.e., by June 30, 2023. To allow a reasonable amount of time for providers and suppliers to submit Part B claims, CMS will use Part B claims data for the dates of service described above that have been submitted no later than 30 days after May 31, 2023, i.e., by June 30, 2023.
- For each potential qualifying single source drug as described in section 30.1 of this revised guidance, CMS will use the PDE data to calculate the Total Expenditures under Part D and CMS will use the Part B claims data to calculate the total allowed charges under Part B, inclusive of beneficiary cost sharing, for purposes of determining Total Expenditures under Part B. CMS is clarifying in this revised guidance that expenditures for a drug or biological product that are bundled or packaged into the payment for another service will be excluded from the calculation of total allowed charges under Part B.
- CMS will exclude from the final list of qualifying single source drugs for initial price applicability year 2026 any drugs for which the sum of Total Expenditures under Part D and Part B is less than $200 million.

[40] For purposes of this revised guidance, CMS defines all days as calendar days unless otherwise specified in statute, guidance, or regulation.

30.1.3 Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

In accordance with section 1192(e)(3)(C) of the Act, CMS will exclude plasma-derived products when identifying qualifying single source drugs as described in section 30.1 of this revised guidance ("the Plasma-Derived Product Exclusion"). For purposes of this exclusion, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling. CMS will refer to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[41] and will refer to the FDA Online Label Repository[42] to verify if the product is derived from human whole blood or plasma. CMS will also consult with FDA as needed.

30.2 Identification of Negotiation-Eligible Drugs for Initial Price Applicability Year 2026

In accordance with sections 1192(a) and 1192(d)(1) of the Act, a negotiation-eligible drug for initial price applicability year 2026 is a qualifying single source drug that is among the 50 qualifying single source drugs with the highest Total Expenditures under Part D. CMS will identify the negotiation-eligible drugs for initial price applicability year 2026 as follows:

- CMS will identify all qualifying single source drugs for initial price applicability year 2026 using the process described in section 30.1 of this revised guidance. CMS will exclude any drugs that qualify for the exclusions listed in sections 30.1.1 – 30.1.3 of this revised guidance.
- CMS will identify PDE data for each NDC-11 of a qualifying single source drug for dates of service during the 12-month period beginning June 1, 2022, and ending May 31, 2023. To allow a reasonable time for Part D plan sponsors to submit PDE data, CMS will use PDE data for the dates of service described above that have been accepted no later than 30 days after May 31, 2023, i.e., by June 30, 2023.
- CMS will use this PDE data to calculate the Total Expenditures under Part D for each qualifying single source drug during the 12-month applicable period.
- CMS will (1) remove drugs that are subject to the exception for small biotech drugs, described in section 30.2.1 of this revised guidance; (2) rank the remaining qualifying single source drugs by Total Expenditures under Part D during the applicable 12-month period; and (3) identify the 50 qualifying single source drugs that have the highest Total Expenditures under Part D during the applicable 12-month period.
- These 50 drugs will be considered negotiation-eligible drugs for initial price applicability year 2026.

When two or more qualifying single source drugs have the same Total Expenditures to the dollar under Part D, and such Total Expenditures are the 50th highest among qualifying single source drugs, CMS will rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, for the initial FDA application number with its active moiety(ies) / active ingredient(s), until CMS has identified 50 negotiation-eligible drugs. CMS believes that this approach would not be likely to alter which drugs are selected drugs because a maximum of 10 drugs will be selected for initial price applicability year 2026 (see section 30.3 of this revised guidance for details).

[41] See: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.
[42] See: https://labels fda.gov/.

30.2.1 Exception for Small Biotech Drugs

In accordance with section 1192(d)(2) of the Act, the term "negotiation-eligible drug" excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs ("the Small Biotech Exception"). The statute requires that CMS consider, for Part D drugs, Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures for the qualifying single source drug under Part D during 2021, and Total Expenditures under Part D for all covered Part D drugs for which the manufacturer that had a Coverage Gap Discount Program (CGDP) agreement in effect under section 1860D-14A of the Act for the qualifying single source drug during 2021 also had a CGDP agreement in effect during 2021.[43] To identify and exclude such small biotech drugs, CMS will consider whether, for dates of services in calendar year 2021, the Total Expenditures under Part D for the qualifying single source drug (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the qualifying single source drug had a CGDP agreement in effect during 2021.

For the purposes of the Small Biotech Exception for initial price applicability year 2026, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all entities that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 with the entity that had the CGDP agreement for the qualifying single source drug on that date. However, CMS does not have information about which entities were treated as a single employer under the applicable IRC provisions. Therefore, a manufacturer that seeks the Small Biotech Exception for its qualifying single source drug ("Submitting Manufacturer") must submit information to CMS about the company and its products in order for the drug to be considered for the exception. To the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the NDA(s) / BLA(s) for the qualifying single source drug may be the Submitting Manufacturer. CMS made this decision to ensure that only the entity with which CMS would negotiate in the event that the qualifying single source drug is selected for negotiation, as described in section 40 of this revised guidance, is able to seek the Small Biotech Exception.

On January 24, 2023, CMS released the Small Biotech Exception ICR (CMS-10844 / OMB 0938-1443) to detail the specific data that CMS is requesting for purposes of implementing this exception. The comment period in response to the 60-day notice closed on March 27, 2023. CMS released a revised version of the Small Biotech Exception ICR on April 24, 2023, and the comment period in response to the 30-day Federal Register notice closed on May 24, 2023. CMS published the final, approved version of the Small Biotech Exception ICR on May 26, 2023.[44]

[43] For the purposes of this determination, a manufacturer that participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's CGDP agreement would be considered to have had an agreement in effect during 2021.

[44] To view the Small Biotech ICR Form, a summary of changes made to the Small Biotech ICR in response to comments received during the 60-day and 30-day notice periods, as well as comments received on the Small Biotech ICR and CMS' responses to those comments, see https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016.

The Small Biotech Exception ICR addresses the collection of information for initial price applicability year 2026 only. For initial price applicability year 2026, Sections 1191(a) and 1192(d) of the Act require CMS to evaluate whether a qualifying single source drug qualifies as a negotiation-eligible drug under 1192(d) based on Total Expenditures under Part D only, including with respect to the Small Biotech Exception. As a result, this ICR addresses the collection of information relevant to Total Expenditures only under Part D. Additionally, this ICR does not address the collection of information relevant to the statutory limitation found in section 1192(d)(2)(B)(ii) of the Act (which precludes the application of the Small Biotech Exception to a qualifying single source drug if the manufacturer of that drug is acquired after 2021 by a manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) because the earliest effective date specified in that limitation (January 1, 2025) has no impact until initial price applicability year 2027 (the first initial price applicability year with a selected drug publication date after January 1, 2025).

As CMS announced on May 26, 2023, after approval of the ICR, to receive consideration for the Small Biotech Exception for initial price applicability year 2026, the Submitting Manufacturer must submit the Small Biotech Exception ICR Form using the CMS Health Plan Management System (CMS HPMS) by July 3, 2023.[45] CMS will notify the Submitting Manufacturer in September 2023 of the determination of whether the Submitting Manufacturer's qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026. CMS is clarifying in this revised guidance that information in a Small Biotech Exception ICR Form that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)).

CMS will not consider incomplete submissions. Upon receipt of a complete Small Biotech Exception ICR Form, CMS will take the following approach to identify whether a qualifying single source drug qualifies for the Small Biotech Exception:

- CMS will identify the manufacturer that had a CGDP agreement for the qualifying single source drug in effect as of December 31, 2021 ("2021 Manufacturer") based on the information submitted in the Small Biotech Exception ICR Form.
- CMS will use the information submitted in that form to identify the complete set of 11-digit National Drug Codes (NDC-11s)[46] for which any member of the 2021 Manufacturer's controlled group as of December 31, 2021 had a CGDP agreement as of December 31, 2021. "Controlled group" means all corporations or partnerships, proprietorships and other entities treated as a single employer under 26 U.S.C. § 52(a) or (b).
- Using the complete set of NDC-11s for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect on December

[45] On June 2, 2023, CMS released the Small Biotech Exception functionality in CMS HPMS, and manufacturers could begin submitting their requests on that date. To view instructions for requesting the Small Biotech Exception in CMS HPMS, see https://www.cms.gov/files/document/small-biotech-exception-guidance-6223.pdf.

[46] NDC-9 and NDC-11 numbers are identical except for two numbers in NDC-11s that indicate package size. Because of this, NDC-11 is more granular than NDC-9, and multiple NDC-11 numbers can aggregate under a single NDC-9 number.

31, 2021, CMS will identify PDE data for dates of service during the 12-month period beginning January 1, 2021 and ending December 31, 2021.

- Using the PDE data for (1) the qualifying single source drug, (2) the complete set of covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement as of December 31, 2021, and (3) all covered Part D drugs, CMS will determine whether:
    - The Total Expenditures under Part D for the qualifying single source drug were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and
    - The Total Expenditures under Part D for the qualifying single source drug were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect during 2021.

  CMS is clarifying in this revised guidance that the Total Expenditures under Part D for all covered Part D drugs will be determined using PDE data for all covered Part D drugs. The Total Expenditures under Part D for the qualifying single source drug and the Total Expenditures under Part D for all covered Part D drugs for which the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group had a CGDP agreement in effect during 2021 will only include PDE data for NDC-11s with labeler codes associated with the 2021 Manufacturer or any member of the 2021 Manufacturer's controlled group.

For initial price applicability year 2026, the term "negotiation-eligible drug" will exclude any covered Part D drugs that are qualifying single source drugs that meet these criteria to qualify for the Small Biotech Exception.

A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years. The Submitting Manufacturer must resubmit a request for the drug to be considered for the exception for initial price applicability years 2027 and 2028. The process for resubmitting a request will be addressed in future guidance.

In this revised guidance, CMS is clarifying that it will publish the number of drugs that applied for and received the Small Biotech Exception for initial price applicability year 2026 as part of publishing the selected drug list on September 1, 2023.

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2026

In accordance with sections 1192(a) and 1192(b) of the Act, CMS will select 10 (or all, if such number is less than 10) negotiation-eligible drugs for initial price applicability year 2026 as follows:

- CMS will rank the 50 negotiation-eligible drugs identified in section 30.2 of this revised guidance by Total Expenditures under Part D (based on the data described in section 30.2 of this revised guidance) in descending order: the negotiation-eligible drug with the highest Total Expenditures under Part D will be listed first and the negotiation-eligible drug with the lowest Total Expenditures under Part D will be listed last.

- CMS will remove any biological products that qualify for delayed selection under section 1192(f) of the Act as described in section 30.3.1 of this revised guidance.
- CMS will select for negotiation the 10 (or all, if such number is less than 10) highest ranked negotiation-eligible drugs remaining on the ranked list for initial price applicability year 2026.
    - In the event that two or more negotiation-eligible drugs have the same Total Expenditures under Part D to the dollar and such Total Expenditures are the 10th highest among negotiation-eligible drugs, CMS will rank those negotiation-eligible drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the initial FDA application number for its active moiety(ies) / active ingredient(s), and select based on that ranking until there are 10 selected drugs (or until all drugs are selected if the number of negotiation-eligible drugs is less than 10).

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

In accordance with section 1192(b)(1)(C) of the Act, CMS will remove from the ranked list of 50 negotiation-eligible drugs described in section 30.3 of this revised guidance any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. This section 30.3.1 describes the implementation of section 1192(f) of the Act (the "Biosimilar Delay").

Under section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by FDA. CMS believes that this approach is appropriate because (1) it clearly identifies one manufacturer that may submit a Biosimilar Delay request for a given Biosimilar, avoiding the possibility that CMS would receive two such requests naming the same Biosimilar for the same initial price applicability year, and (2) the status of the application for licensure for the Biosimilar is material to CMS' consideration of a Biosimilar Delay request, as described in this section 30.3.1.

Section 1192(f) of the Act contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year ("Additional Delay Request") as stated in section 1192(f)(1)(B)(i)(II) of the Act.

The following subsections of this section 30.3.1 include details on the implementation of the Biosimilar Delay for initial price applicability year 2026. Topics related to future initial price applicability years (including Additional Delay Requests) will be covered in future guidance.

30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026

The statute specifies that the following requirements must be met in order for CMS to grant an Initial Delay Request:

1. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be, absent the Biosimilar Delay, a selected drug for the initial price applicability year.
    - Biosimilar Manufacturers that think that a Reference Drug for their Biosimilar may be a selected drug for initial price applicability year 2026 may submit an Initial Delay Request, and CMS will disregard that application if the Reference Drug would not, in fact, be a selected drug for initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug.
2. In accordance with section 1192(f)(1)(A) of the Act, it is required that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests submitted with respect to initial price applicability year 2026, this means that the Reference Drug must have received its initial BLA licensure between January 1, 2010, and January 1, 2014.
    - Section 1194(c)(4)(B)(ii) of the Act specifies that selected drugs for which a manufacturer had an agreement under the Negotiation Program for an initial price applicability year prior to 2030 are excluded from the definition of extended-monopoly drugs. Importantly, however, an Initial Delay Request must be submitted by a Biosimilar Manufacturer before the selected drug publication date for an initial price applicability year and before the Primary Manufacturer (as defined in section 40 of this revised guidance) of the Reference Drug ("Reference Manufacturer") would have entered into an agreement under the Negotiation Program. Therefore, CMS believes the exception to the definition of "extended-monopoly drug" in section 1194(c)(4)(B)(ii) of the Act will not apply at the time that a delay would be requested for initial price applicability years 2026 through 2029. Accordingly, CMS believes that the Biosimilar Delay under section 1192(f) of the Act is applicable beginning with initial price applicability year 2026. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2026, provided that the Reference Drug named in the request will have been licensed for between 12 and 16 years prior to the start of the initial price applicability year on January 1, 2026.
3. In accordance with section 1192(f)(1)(A) of the Act, the Reference Drug must include the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved by the FDA or accepted for review, as described below in section 30.3.1.2 of this revised guidance.
    - Please note that in order for CMS to grant an Initial Delay Request, the licensure application for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval.

4. In accordance with section 1192(f)(2)(D)(iii) of the Act, an Initial Delay Request cannot be granted if more than one year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
    - For Initial Delay Requests submitted with respect to initial price applicability year 2026, this requirement means that if the Biosimilar has already received approval by the FDA for its application for licensure under section 351(k) of the PHS Act, the date of such licensure must be on or after September 1, 2022 for a delay to be granted. If the Biosimilar is already licensed and marketed by September 1, 2023, the selected drug publication date for initial price applicability year 2026, the Reference Drug would by definition no longer be a qualifying single source drug and therefore would fail requirement #1 on this list. If the Biosimilar was licensed prior to September 1, 2022 and is not marketed before September 1, 2023, more than one year would have elapsed since the licensure of the Biosimilar without marketing of the Biosimilar having commenced.
5. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same pursuant to section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC of 1986, or in a partnership, shall be treated as one manufacturer, as stated in section 1192(f)(1)(C) of the Act.
    - For the purposes of this determination, "partnership" is defined at section 1192(f)(1)(C)(ii) of the Act as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer.
6. In accordance with section 1192(f)(2)(D)(iv) of the Act, the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that either:
    - requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request; or
    - directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time. For Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after September 1, 2023 as violating this requirement.
7. In accordance with section 1192(f)(1)(A) of the Act and as described in detail in section 30.3.1.2 of this revised guidance, CMS must determine that there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year.

30.3.1.2 High Likelihood

In accordance with section 1192(f)(1)(A) of the Act, CMS will review Initial Delay Requests to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the date that is two years after the selected drug publication date for the initial price applicability year. Accordingly, for Initial Delay Requests submitted with respect to initial price

applicability year 2026, CMS must find a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, in order to grant the request. If CMS does not find that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described below, CMS will deny the Initial Delay Request.

In accordance with section 1192(f)(3) of the Act, Initial Delay Requests must demonstrate both of the following in order meet the high likelihood threshold:

1. An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA.[47]
    - For Initial Delay Requests submitted with respect to initial price applicability year 2026, the Biosimilar's application for licensure must be approved or accepted for review by the FDA no later than August 15, 2023, in order to permit CMS time to review the information and finalize the selected drug list prior to the selected drug publication date of September 1, 2023.
    - Please note that if the Biosimilar's application for licensure has not been accepted for review by August 15, 2023, including in the case where the Biosimilar Manufacturer has submitted an application for licensure that has not been accepted for review by the FDA or for which a filing determination is pending, CMS will deny the Initial Delay Request for initial price applicability year 2026.
2. Clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025 (the date that is two years after the selected drug publication date for the initial price applicability year), based on the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS.

For Initial Delay Requests submitted for initial price applicability year 2026, to demonstrate clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025, CMS requires that the information from the items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act as submitted to CMS by the Biosimilar Manufacturer as part of its Initial Delay Request demonstrates both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the U.S. to date, and so CMS believes that evidence showing that a Biosimilar meets these two requirements is sufficient to establish clear and convincing evidence that the Biosimilar will be marketed.

First, the Initial Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before September 1, 2025. CMS is clarifying in this revised guidance that, in its evaluation of whether this requirement is met, CMS will only consider patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. Specifically, CMS will consider this requirement met if (1) there are no unexpired patents relating to the reference product included in the Reference

[47] CMS is clarifying in this revised guidance that it will consider an application for licensure under section 351(k) of the PHS Act that has been accepted for review and that received a Complete Response letter to meet the section 1192(f)(3)(A) requirement that an application for licensure under section 351(k) for the biosimilar biological product has been accepted for review by FDA.

Drug that are applicable to the Biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer.[48] CMS will deny all Initial Delay Requests for Biosimilars that do not meet this requirement with respect to at least one reference product included in the Reference Drug. However, active litigation related to another reference product included in the Reference Drug that is not applicable to the Biosimilar will not be disqualifying.

Second, the Initial Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before September 1, 2025. To assess this requirement, CMS will consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before September 1, 2025, and (2) a manufacturing schedule that is consistent with the public-facing statements and, as clarified in this revised guidance, demonstrates readiness to meet revenue expectations. CMS chose these criteria because they are indicative of operational readiness and should be available in the elements that CMS must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act.

In determining whether an Initial Delay Request satisfies the high likelihood threshold, CMS may use all the information described in section 30.3.1.3 of this revised guidance to determine whether an application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by the FDA. In accordance with section 1192(f)(3)(B) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar will be marketed before September 1, 2025:

- All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and
- Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the two years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies.

[48] As described in section 30.3.1.1 of this revised guidance, an Initial Delay Request will not be granted if the Biosimilar Manufacturer enters into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request or directly or indirectly restricts the quantity of the Biosimilar sold in the United States on or after September 1, 2023.

In accordance with section 1198(2) of the Act, there will be no administrative or judicial review of CMS' determinations under section 1192(f) of the Act.

30.3.1.3 Submitting an Initial Delay Request for Initial Price Applicability Year 2026

A Biosimilar Manufacturer intending to submit an Initial Delay Request for initial price applicability year 2026 was required to submit a complete request by 11:59 pm PT on May 22, 2023. The process for Biosimilar Manufacturers to submit an Initial Delay Request, including the required documentation, for initial price applicability year 2026 is detailed below.

A Biosimilar Manufacturer should have submitted an Initial Delay Request for initial price applicability year 2026 only if it (1) plans for its Biosimilar to be licensed and marketed before September 1, 2025, (2) believes its request will satisfy the statutory requirements for granting an Initial Delay Request, as described in section 30.3.1.1 of this revised guidance, and (3) believes that its request demonstrates that there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025, based on the criteria described in section 30.3.1.2 of this revised guidance.[49]

CMS has designed the process for Initial Delay Request submission for initial price applicability year 2026 to allow CMS time to adjudicate all requests in advance of September 1, 2023, the selected drug publication date, and to be operationally feasible. For initial price applicability year 2026, CMS accepted Initial Delay Requests submitted via email and Box[50] as described below, whereas, for future initial price applicability years, CMS plans to issue guidance on use of the CMS HPMS to receive and process these requests. Accordingly, Initial Delay Requests for initial price applicability year 2026 were able to be submitted via the following process:

1. The Biosimilar Manufacturer emailed IRARebateandNegotiation@cms.hhs.gov to indicate its intention to submit an Initial Delay Request for initial price applicability year 2026. The Biosimilar Manufacturer was encouraged to use the template, including subject line and body content, described in Appendix A of this revised guidance. Emails must have been received by 11:59 pm PT on May 10, 2023.
2. Within 5 business days of receipt, CMS responded by providing the Biosimilar Manufacturer with (1) a fillable template for the Initial Delay Request form, available in Appendix B of this revised guidance, and (2) access to a Box folder specific to the Biosimilar Manufacturer's Initial Delay Request. No parties other than the Biosimilar Manufacturer and CMS and its contractors have access to this folder.
3. The Biosimilar Manufacturer must have uploaded a complete Initial Delay Request with the following documentation to the Box folder or using an alternative submission approach approved by CMS by 11:59 pm PT on May 22, 2023. CMS deemed an Initial Delay Request to be complete if it included:

[49] For initial price applicability year 2026, an Initial Delay Request should have been submitted by a Biosimilar Manufacturer that anticipated the reference product for its Biosimilar will be included in one of the ten covered Part D Drugs that will be a selected drug for this initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for covered Part D drugs, including data published by CMS, which may allow them to determine the likelihood that a given drug may be a selected drug for a future initial price applicability year.

[50] See: https://www.box.com/; if a Biosimilar Manufacturer is unable to use Box, it should have included an explanation in its email in step #1 below and request an alternative submission method.

a. A complete Initial Delay Request form using the fillable template that the Biosimilar Manufacturer received from CMS. This template allowed submission of:
    i. information used to identify the Biosimilar Manufacturer, the Biosimilar, the Biosimilar's reference product, and the Reference Manufacturer;
    ii. attestations that the Initial Delay Request meets the statutory requirements listed in section 30.3.1.1 of this revised guidance; and
    iii. information on the status of licensure for the Biosimilar under section 351(k) of the PHS Act;
b. All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
c. The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
d. Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the two years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.

In accordance with section 1192(f)(1)(B)(ii) of the Act, Initial Delay Requests for initial price applicability year 2026 that were not submitted by 11:59 pm PT on May 22, 2023 or that did not include all elements will be denied. CMS is clarifying in this revised guidance that information in an Initial Delay Request that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).

30.3.1.4 Process and Timing After Submission of an Initial Delay Request for Initial Price Applicability Year 2026

Within 5 business days after the Biosimilar Manufacturer uploaded the required documentation to its Box folder or using an alternative submission approach approved by CMS, CMS sent an email confirming receipt to the email address used by the Biosimilar Manufacturer in its initial email to CMS expressing its intent to submit an Initial Delay Request. In accordance with section 1192(f)(1)(B)(ii)(II) of the Act, after reviewing an Initial Delay Request, inclusive of the materials submitted therein, CMS may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request. For initial price applicability year 2026, CMS made any such follow-up request in writing to the Biosimilar Manufacturer via the same email address on or before June 20, 2023. Any such written request specified the additional information required, the format and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information, which will be no later than July 3, 2023. The one exception to these deadlines

is as follows: per section 30.3.1.2 of this revised guidance, for CMS to determine that there is a high likelihood of the Biosimilar being licensed and marketed prior to September 1, 2025, the Biosimilar's application for licensure must be accepted for review or approved by the FDA no later than August 15, 2023. CMS will permit the Biosimilar Manufacturer to update CMS on the status of the Biosimilar's application for licensure before 11:59 pm Pacific Time (PT) on August 15, 2023, in order to enable CMS to use the most recent possible data to make this determination while still allowing for sufficient time to inform the selected drug list published on September 1, 2023, in accordance with section 1192(a) of the Act.

Prior to September 1, 2023, the selected drug publication date for initial price applicability year 2026, CMS will review each Initial Delay Request in the following manner. First, CMS will review each Initial Delay Request to determine whether it includes all of the elements for an Initial Delay Request and was submitted by the applicable deadline in accordance with section 30.3.1.3 of this revised guidance. Second, if an Initial Delay Request includes all required elements and was timely submitted, CMS will review the Initial Delay Request to determine if it meets all of the statutory requirements described in section 30.3.1.1 of this revised guidance, with the exception of the high likelihood requirement. Third, if the Initial Delay Request meets all statutory requirements other than the high likelihood requirement, CMS will review the Initial Delay Request to determine whether it demonstrates a high likelihood that the Biosimilar will be licensed and marketed by September 1, 2025, as described in section 30.3.1.2 of this revised guidance. In considering an Initial Delay Request, CMS will cease consideration upon finding that the Initial Delay Request has failed to meet any of these requirements. For example, if CMS determines an Initial Delay Request was not submitted by the established deadline, CMS will not review that request against other statutory requirements; if CMS determines an Initial Delay Request fails to meet one or more of the statutory requirements described in section 30.3.1.1 of this revised guidance, with the exception of the high likelihood requirement, CMS will not consider whether that Initial Delay Request demonstrates a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

The list of selected drugs published for initial price applicability year 2026 will reflect the results of CMS' determinations with respect to any Initial Delay Requests that are submitted, i.e., a Reference Drug that, absent a successful Initial Delay Request, would have been selected, will not appear on the selected drug list published by September 1, 2023 if it is named in a successful Initial Delay Request.

After completing its review, CMS will notify each Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2026 in writing of CMS' determination regarding such request. This notification will occur on or after September 1, 2023, but no later than September 30, 2023, and will include a brief summary of CMS' determination, including:

- Whether the Initial Delay Request was successful or unsuccessful; and
- If unsuccessful, the reason CMS determined that the Initial Delay Request was unsuccessful, including but not limited to:
    - failure to submit all elements of the Initial Delay Request by the applicable deadline;
    - failure to meet another statutory requirement for granting a request (other than the high likelihood requirement), including in the case that the Reference Drug would

not have been a selected drug for initial price applicability year 2026 absent the Initial Delay Request; or

- failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025.

CMS will also notify each Reference Manufacturer named in a successful Initial Delay Request using the CMS HPMS to identify the relevant point(s) of contact. Such notification will be in writing and will identify the Reference Drug that would have been a selected drug in initial price applicability year 2026, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests will not be notified. In this revised guidance, CMS is clarifying that it will publish the number of Reference Drugs that would have been selected drugs for initial price applicability year 2026, absent successful Initial Delay Requests, as part of publishing the selected drug list on September 1, 2023.

In accordance with section 1192(f)(2)(B) of the Act, CMS must determine whether each Biosimilar named in a successful Initial Delay Request is licensed and marketed during the initial delay period. For successful Initial Delay Requests submitted with respect to initial price applicability year 2026, CMS will make this determination by mid-2024; CMS is still determining the appropriate date by which this determination should be made and plans to publish a specific date in future guidance. The timing, content, and format of this notification will be specified in future guidance.

The following table provides a summary of key dates related to implementation of the Biosimilar Delay for initial price applicability year 2026, as specified in this section 30.3.1:

Date	Deadline / milestone
11:59 pm PT on May 10, 2023	Deadline for Biosimilar Manufacturer to email CMS regarding intent to submit Initial Delay Request for initial price applicability year 2026
11:59 pm PT on May 22, 2023	Deadline for Biosimilar Manufacturer to submit the documentation for its Initial Delay Request as specified in section 30.3.1.3 of this revised guidance
June 20, 2023	Deadline for CMS to request follow-up information for a submitted Initial Delay Request, if applicable
July 3, 2023	Deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS, if applicable
11:59 pm PT on August 15, 2023	Deadline for Biosimilar application for licensure to be accepted for review or approved by the FDA; deadline for Biosimilar Manufacturer to submit any follow-up information requested by CMS related to the Biosimilar application for licensure
September 1, 2023	Statutory deadline for CMS to publish the selected drug list for initial price applicability year 2026. Along with the selected drug list, CMS will publish the number of drugs that would have been selected drugs, absent successful Initial Delay Requests.
September, 2023	CMS informs each Biosimilar Manufacturer that submitted an Initial Delay Request of the results of such request, in writing; for successful Initial Delay Requests, CMS also informs the Reference Manufacturer
Mid-2024[51]	For successful Initial Delay Requests, CMS determines whether the Biosimilar has been licensed and marketed during the initial delay period

Information on other policies related to section 1192(f) of the Act will be included in future guidance, including, but not limited to:

- the deadline and process for submitting an Initial Delay Request for initial price applicability year 2027;
- the deadline and process for submitting an Additional Delay Request for initial price applicability year 2027, in the event an Initial Delay Request for initial price applicability year 2026 is granted and CMS determines by mid-2024 that the Biosimilar was not licensed and marketed during the initial delay period;[52]
- the criteria for adjudicating Additional Delay Requests;
- the impact of Initial Delay Requests and Additional Delay Requests on the selected drug list for initial price applicability year 2027; and
- the application and calculation of rebates for a Reference Drug for 2026, as applicable.

30.4 Publication of the Selected Drug List

In accordance with section 1192(a) of the Act, CMS will publish the selected drug list for initial price applicability year 2026 no later than September 1, 2023. This list will include the 10 (or all, if such number is less than 10) drugs selected for negotiation for initial price applicability year 2026, including the active moiety / active ingredient for each selected drug, and the list of NDC-9s and NDC-11s for the selected drug that either had PDE utilization in the 12-month period

[51] CMS plans to publish a specific date in future guidance.
[52] CMS plans to publish a specific date in future guidance.

beginning June 1, 2022 and ending May 31, 2023 or that CMS believes are likely to have PDE utilization in the future (for example, NDC-11s associated with recently approved NDAs / BLAs).[53] CMS will post the selected drug list on the CMS IRA webpage and update this list in accordance with the process described in section 40.2 of this guidance.[54]

40. Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026

In accordance with section 1193(a) of the Act, the Secretary shall enter into agreements with manufacturers of selected drugs. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be "the manufacturer" of the selected drug (hereinafter "Primary Manufacturer").

Likewise, for initial price applicability year 2026, CMS will refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on the NDA or BLA as a "Secondary Manufacturer." A Secondary Manufacturer will include any manufacturer of any authorized generics and any repackager or relabeler of the selected drug that meet these criteria. A manufacturer that is not listed as a manufacturer on the NDA / BLA and without an agreement in place with the Primary Manufacturer would not be considered a Secondary Manufacturer.

In the example described in section 30.1 of this revised guidance, if the potential qualifying single source drug described was selected for negotiation, entity "A" would be considered the Primary Manufacturer while entity "B" would be considered a Secondary Manufacturer either because it was listed as a manufacturer in NDA-1 or if it was not listed as a manufacturer in NDA-1 because it markets the three strengths of the immediate release tablets manufactured by entity A pursuant to an agreement with entity A.

CMS will sign an agreement (a "Medicare Drug Price Negotiation Program Agreement," herein referred to as an "Agreement") with the willing Primary Manufacturer of each selected drug and believes this approach aligns with the statute's requirement to negotiate to determine an MFP with "the manufacturer" of a selected drug in accordance with section 1193(a) of the Act. This Agreement, as described in this section 40, will set forth requirements of the Primary Manufacturer with respect to its participation in the Negotiation Program, including with respect to section 1193(a)(5) of the Act, which requires the Primary Manufacturer to comply with

[53] CMS acknowledges that, for some selected drugs, the list of NDC-9s and NDC-11s might not reflect all NDCs marketed pursuant to the approved NDA(s) / BLA(s). For example, if a selected drug includes one NDC-9 that has no current or future Part D PDE utilization (e.g., the NDC-9 is utilized only in Part B settings of care), that NDC-9 and associated NDC-11s would not be included on the published list of NDC-9s and NDC-11s of the selected drug for initial price applicability year 2026.

[54] See: https://www.cms.gov/inflation-reduction-act-and-medicare.

requirements set forth in this revised guidance, which CMS has determined are necessary for purposes of administering and monitoring compliance with the Negotiation Program.

CMS will not enter into an Agreement with any Secondary Manufacturer of a selected drug with respect to that drug. As such, under section 1193(a)(4), a Primary Manufacturer that enters into an Agreement must collect and report necessary information applicable to any Secondary Manufacturer(s) as described in section 40.2 of this revised guidance. As the entity that is party to the Agreement, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Agreement and will be accountable for ensuring compliance with respect to units of the selected drug manufactured by the Secondary Manufacturer or marketed by any Secondary Manufacturer pursuant to an agreement with the Primary Manufacturer. In accordance with section 1193(a)(1) of the Act and section 40.4 of this revised guidance, the Primary Manufacturer must ensure that any Secondary Manufacturer(s) make the MFP available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers. For initial price applicability year 2026, the scope of Primary Manufacturer responsibility to provide access to the MFP for the selected drug is limited to units of such drug sold by the Primary Manufacturer or a Secondary Manufacturer. CMS reiterates that the requirement for Primary Manufacturers to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as described in section 80 of this revised guidance. Failure to comply with obligations to make the MFP available may result in civil monetary penalties being assessed on the Primary Manufacturer pursuant to section 1197(a) of the Act.

CMS requires that for initial price applicability year 2026, the Primary Manufacturer of a selected drug is the entity that does each of the following:

1. Signs the Agreement with CMS, as described in section 40.1 of this revised guidance;
2. Collects and reports all data required for negotiation under section 1193(a)(4) of the Act, including the negotiation data elements, as described in section 40.2, section 50.1, and Appendix C of this revised guidance;
3. Negotiates an MFP with CMS, as described in section 40.3 of this revised guidance;
4. Ensures the MFP is made available to all MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that dispense the selected drug to those individuals, as described in section 40.4 of this revised guidance; and
5. Responds to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities, and pays any CMPs for violations, including: violating the terms of the Agreement; providing false information under the procedures to apply the aggregation rule for the Small Biotech Exception or the Biosimilar Delay; failing to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but which has since undergone negotiation as described in section 1192(f)(4) of the Act; or not providing access to the MFP to MFP-eligible individuals, pharmacies, mail order services, and other dispensers, as described in section 40.5, section 90, and section 100 of this revised guidance.

Termination of an Agreement for the Negotiation Program is described in section 40.6 of this revised guidance, and other relevant provisions from the Agreement are described in section 40.7. of this revised guidance.

40.1 Entrance into an Agreement with CMS and Alternatives

Section 1193(a) of the Act instructs CMS to enter into agreements with manufacturers of selected drugs for a price applicability period. The deadline for the Primary Manufacturer of a selected drug to enter into an Agreement for initial price applicability year 2026 is October 1, 2023. The Primary Manufacturer must use the CMS HPMS to identify relevant authorized representative(s) and effectuate the Agreement.[55]

CMS recommends, but does not require, that within five days following publication by CMS on September 1, 2023 of the list of selected drugs for an initial price applicability year, the Primary Manufacturer submit to CMS the name(s), title(s), and contact information for the representative(s) authorized to execute the Agreement. CMS recommends taking this action as soon as possible to facilitate timely communication and effectuation of the Agreement. The authorized representative(s) must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Agreement, including any Addenda. The authorized representatives should follow instructions made available on the CMS HPMS webpage to gain access to the CMS HPMS. To be eligible for electronic signature access in CMS HPMS, an authorized representative must be the Primary Manufacturer's Chief Executive Officer, Chief Financial Officer, an individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer, or an individual that has been granted direct delegated authority to perform electronic signatures on behalf of one of the individuals previously noted. CMS notes that it is a requirement of the CMS HPMS that the person accessing the CMS HPMS have a Social Security Number (SSN). An authorized representative of the Primary Manufacturer must access the CMS HPMS and sign the Agreement by October 1, 2023.

The negotiation period for initial price applicability year 2026 will begin on the earlier of two dates: the date on which the Agreement is executed (i.e., signed by both CMS and the Primary Manufacturer) or October 1, 2023. If an Agreement is fully executed before October 1, 2023, the negotiation period (as defined in section 1191(b)(4) of the Act) will begin on the date on which the Agreement is signed by the last party to sign it. If the Agreement is not fully executed by October 1, 2023, then pursuant to 26 U.S.C. § 5000D(b)(1), a period will begin on October 2, 2023, during which the manufacturer could be exposed to potential excise tax liability. CMS will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list for initial price applicability year 2026 is published.

Section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program. If a Primary Manufacturer decides it is unwilling to enter into an Agreement for the Negotiation Program, it may expedite its exit from the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program by submitting to CMS a notice that incorporates both: (1) a notice of decision not to participate in the Negotiation Program; and

[55] See: https://hpms.cms.gov/app/ng/home/.

(2) a request for termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program, the Medicare Coverage Gap Discount Program, and the Manufacturer Discount Program. When a Primary Manufacturer submits such a notice, CMS will find good cause to terminate the Primary Manufacturer's agreement(s) under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14A(b)(4)(B)(i) and section 1860D-14C(b)(4)(B)(i) of the Act to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under section 1860D-14A or section 1860D-14C. CMS has determined (and hereby provides notice) that it will automatically grant such termination requests upon receipt, and that it will expedite the effective date of the Primary Manufacturer's termination of its Medicare Coverage Gap Discount Program and/or Manufacturer Discount Program agreements consistent with the statutory limitation that termination shall not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination.

If a Primary Manufacturer has determined it would not be willing to enter into an Agreement for the Negotiation Program if one of its drugs is listed as a selected drug and has submitted a notice of its decision and its request for termination as described above, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning its termination request. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its termination request.

40.2 Submission of Manufacturer Data to Inform Negotiation

After entering into an Agreement with CMS and in accordance with section 1193(a)(4) of the Act, the Primary Manufacturer of each selected drug must submit to CMS the following information with respect to the selected drug: information on the non-Federal average manufacturer price ("non-FAMP") (defined in section 8126(h)(5) of title 38, United States Code), as described in section 50.1.1 and Appendix C of this revised guidance, and any information that CMS requires to carry out negotiation, including but not limited to the factors listed in section 1194(e)(1) of the Act, as described in section 50.1 and Appendix C of this revised guidance. This information must be submitted by the Primary Manufacturer to CMS no later than October 2, 2023, for initial price applicability year 2026.

The Agreement must be fully executed, meaning both the Primary Manufacturer and CMS have signed the Agreement, before the Primary Manufacturer may submit the data elements described in this section. While these data elements may not be submitted prior to execution of the Agreement, Primary Manufacturers will be able to access the data elements template in the CMS HPMS, and CMS believes Primary Manufacturers will be able to gather these data prior to the Agreement being executed. By signing the Agreement, a Primary Manufacturer agrees to use the CMS HPMS and comply with all relevant procedures and policies set forth in the CMS HPMS for utilizing the system.

Certain data, as described in section 50.1 and Appendix C of this revised guidance, must reflect any products included in the selected drug marketed by a Secondary Manufacturer(s), and the Primary Manufacturer is responsible for collecting such data from such Secondary Manufacturer(s) and including this information in its submission to CMS.

For each selected drug for initial price applicability year 2026, CMS will populate the CMS HPMS with the list of the NDC-11s published in accordance with section 30.4 of this revised guidance, meaning those NDC-11s of the selected drug that either had Part D PDE utilization in the 12-month period beginning June 1, 2022 and ending May 31, 2023 or which CMS believes are likely to have PDE utilization in the future (for example, NDC-11s associated with recently approved NDAs / BLAs). This list will include any NDC-11s of the selected drug marketed by the Primary Manufacturer and any Secondary Manufacturer. CMS will transmit the list to the Primary Manufacturer of the selected drug. In connection with the data submission described in section 50.1 of this revised guidance, the Primary Manufacturer must provide CMS with information regarding the NDC-11s that may be appropriate to ensure the list is complete and accurate, including but not limited to, whether any NDC-11s associated with the NDA(s) / BLA(s) of the selected drug are missing from the list (e.g., because they are new NDC-11s), including any missing NDC-11s of a Secondary Manufacturer of the selected drug; whether any of the listed NDC-11s are marketed or controlled solely by a manufacturer that is not the Primary Manufacturer or a Secondary Manufacturer; and whether any of the listed NDC-11s have been discontinued. CMS will collect this information in the CMS HPMS as part of the collection of the other data elements described in section 50.1 of this revised guidance and update this list as necessary (e.g., based on supplements from the Primary Manufacturer or other updates).

This list of NDC-11s constitutes the baseline of NDCs of the selected drug as described in section 30 of this revised guidance that will be subject to the negotiation process for initial price applicability year 2026. The NDC-11s on this list will be included in ceiling calculations for initial price applicability year 2026 as described in section 60.2, to the extent data are available to support such calculations. CMS will also use the NDC-11s on this list for the calculations used to apply the MFP across dosage forms and strengths of the selected drug for initial price applicability year 2026 as described in section 60.5 of this revised guidance. In addition, CMS will use the information supplied by the Primary Manufacturer about discontinued NDC-11s as additional context for the data elements described in section 50.1 of this revised guidance (e.g., notice that an NDC-11 has been discontinued may explain why a Primary Manufacturer submitted partial year data for a particular NDC-11 of a selected drug).

The Primary Manufacturer has an ongoing obligation to timely report any changes in this information to ensure the list of NDC-11s of the selected drug in the CMS HPMS remains complete and accurate consistent with this revised guidance and any future guidance and regulations. For example, a Primary Manufacturer must report to CMS any new NDC-11s of the selected drug at least 30 days prior to their first marketed date for any Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug; if CMS believes these new NDC-11s are likely to have PDE utilization in the future, these NDC-11s will be added to the list of NDC-11s of the selected drug. The Primary Manufacturer also must report to CMS the delisting of any NDC-11 of the selected drug that is no longer marketed by the Primary Manufacturer or any

Secondary Manufacturer(s) within 30 days after its discontinuation. Failure of the Primary Manufacturer to provide timely information material to the accuracy of the list of NDC-11s of the selected drug as described in this section 40.2 of the revised guidance will be considered a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to civil monetary penalties per section 1197(c) of the Act.

40.2.1 Confidentiality of Proprietary Information

Section 1193(c) of the Act states that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secrets and confidential commercial or financial information, will also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. § 552(b)(3), (4)).[56]

CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary. Thus, for initial price applicability year 2026, CMS will treat information on non-FAMP as proprietary.

For initial price applicability year 2026, CMS will also treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section 1194(e)(2) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. Specifically, CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS understands these data are publicly available.

Pursuant to section 1195(a)(2) of the Act, CMS is required to publish the explanation of the MFP by March 1, 2025, for initial price applicability year 2026 (see section 60.6.1 of this revised guidance). In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer and the public that are determined to be non-proprietary, but will not include any protected health information (PHI) or personally identifiable information (PII). CMS will also make public high-level comments about the section 1194(e)(1) and section 1194(e)(2) data submitted to CMS that are determined to be proprietary, without sharing any PHI / PII or any proprietary information reported to CMS under section 1193(a)(4) for purposes of the negotiation. For example, CMS will not make public the research and development costs

[56] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may say "the manufacturer has recouped its research and development costs." Any proprietary information obtained during the course of an audit will also remain confidential, except as necessary to use that information in the course of a judicial enforcement proceeding.

40.2.2 Data and Information Use Provisions and Limitations

CMS will not publicly discuss ongoing negotiations with a Primary Manufacturer, except as outlined below. As described in section 60.6.1, CMS will make public a narrative explanation of the negotiation process and share redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable.

Primary Manufacturers may choose to publicly disclose information regarding its ongoing negotiations with CMS at its discretion. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS will no longer consider that material proprietary consistent with section 40.2.1 of this guidance. For example, if a Primary Manufacturer chooses to publicly disclose the unit cost of production, CMS will no longer consider the unit cost of production to be proprietary. If the Primary Manufacturer chooses to disclose proprietary information prior to the explanation of the MFP, then it will not be redacted in the explanation of the MFP. Primary Manufacturers negotiating an MFP with CMS pursuant to the process set forth in section 60 are reminded that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. Information exchanges concerning confidential and strategic business negotiations may violate the antitrust laws under certain circumstances and lead to other anticompetitive agreements. Primary Manufacturers should consider the antitrust implications of any such actions.

CMS will prohibit audio or video recording of any negotiation meetings between CMS and a Primary Manufacturer. CMS will maintain written records of the negotiation process, including negotiation meetings, in compliance with applicable federal law, including the Federal Managers Financial Integrity Act and the Federal Records Act. A Primary Manufacturer can maintain its own written record of these exchanges.

40.2.3 Opportunity for Corrective Action Following Information Submission

Recognizing the substantial role that manufacturer-submitted information will play in the negotiation process and in administering and monitoring the Negotiation Program, CMS will provide an opportunity for corrective action in the event a submission is incomplete or inaccurate. Upon receipt of Primary Manufacturer-submitted information – for example, information on the section 1194(e)(1) factors – CMS will review the submission for completeness and accuracy. Should CMS determine a submission is incomplete or contains inaccurate information, CMS will provide a written request that the Primary Manufacturer take corrective action and resubmit the information. CMS will provide five business days for the Primary Manufacturer to correct the submission and/or provide additional information to validate

the accuracy/completeness of the original submission. Following resubmission, CMS may follow up with the Primary Manufacturer to clarify any information included in the resubmission and confirm full accuracy and completeness of the required information.

To facilitate the corrective action process, CMS will provide the Primary Manufacturer with a written request for the corrected information, which will be transmitted to the Primary Manufacturer following CMS' discovery of any inaccurate or incomplete submissions. The written request will include a deadline for resubmitting the information (i.e., the end of the five-business day period). CMS will make efforts to be available to engage with the Primary Manufacturer about the specifics of the request for corrected information and to answer questions and provide clarification. Note that failure to engage in timely corrective action may result in the Primary Manufacturer being subject to civil monetary penalties as authorized under section 1197(c) for failure to submit required information.

40.3 Negotiation and Agreement to an MFP and Renegotiation in Later Years

CMS will use the CMS HPMS to share the initial offer and concise justification, any subsequent offer and justification, and to receive any counteroffer(s) from the Primary Manufacturer of a selected drug. A Primary Manufacturer that signs the Agreement will be required to adhere to the process and deadlines described in section 60 of this revised guidance. CMS will also use the CMS HPMS to share and receive an Addendum to the Agreement, as applicable, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP that results from the negotiation process. For example, concurrent with the agency's provision of the initial offer, CMS will populate an Addendum in the CMS HPMS containing the MFP identified in the initial offer; if a Primary Manufacturer wishes to accept CMS' initial offer, it can sign the Addendum in the CMS HPMS. Similarly, concurrent with the Primary Manufacturer's submission of a written counteroffer, the Primary Manufacturer will populate an Addendum in the CMS HPMS containing the MFP identified in the counteroffer and sign the Addendum; if CMS wishes to accept the counteroffer, it will countersign the Addendum in the CMS HPMS. CMS will determine that negotiations have concluded upon execution by both parties of the Addendum setting forth the agreed-upon MFP.

Pursuant to section 1194(f) of the Act, CMS and a Primary Manufacturer may renegotiate the MFP for a selected drug, beginning with 2028. CMS plans to release guidance related to the renegotiation process in future years.

40.4 Providing Access to the MFP

After entering into an Agreement with CMS and in accordance with section 1193(a) of the Act, the manufacturer of a selected drug must provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act and section 80 of this revised guidance) and to pharmacies, mail order services, and other dispensers with respect to such MFP-eligible individuals who are dispensed that drug during a price applicability period. That is, the manufacturer is required to provide access to the MFP for all dosage forms, strengths, and package sizes of the selected drug (i.e., NDCs included in the MFP file published in accordance with section 60.6 of this revised guidance), including any additional such dosage forms, strengths, and package sizes that may be further included in the MFP file, if coverage is being provided for such dosage forms, strengths, and package sizes under a prescription drug plan

under Medicare Part D or an MA–PD plan under Medicare Part C (including an Employer Group Waiver Plan).

Under section 1860D-2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the MFP plus any dispensing fees for such drug. In Part D, the negotiated price of a drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point of sale. Therefore, the requirement that the price used for beneficiary cost-sharing and benefit administration cannot exceed the MFP (plus dispensing fees) helps to ensure that Part D MFP-eligible individuals will have access to the MFP at the point of sale. Therefore, while section 1193(a) of the Act requires manufacturers to provide access to the MFP to MFP-eligible individuals, as a practical matter, this would be facilitated by Part D plan sponsors in the normal course.

However, section 1193(a) of the Act also requires that the manufacturer of a selected drug provide access to the MFP for the selected drug to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed such drugs. CMS requires that the Primary Manufacturer ensures that entities that dispense drugs to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers, have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further described in section 90.2 of this revised guidance. CMS defines "providing access to the MFP" as ensuring that the amount paid by the dispensing entity for the selected drug is no greater than the MFP.

Primary Manufacturers must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. As part of this obligation, the Primary Manufacturer must ensure the MFP is made available to pharmacies, mail order services, and other dispensers for units of the selected drug for which there is a Secondary Manufacturer. With respect to the second option, CMS plans to issue further information regarding the specific calculation that the manufacturer could use in the determination of the refund to the dispenser. CMS is exploring whether manufacturers could offer a standardized refund amount, such as the Wholesale Acquisition Cost (WAC) of the selected drug minus the MFP (WAC-MFP), in order to meet this obligation.

CMS intends to engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between pharmaceutical supply chain entities to support the verification of an MFP-eligible individual who is dispensed a selected drug. CMS intends to continue to work with interested parties to identify existing processes and any new processes that would be the most viable for the supply chain to operationalize to ensure that pharmacies, mail order services, and other dispensers have access to the MFP during the price applicability period. CMS will consult with pharmacies, mail order services, and other dispensers, as well as with industry standard development organizations (SDOs), 340B covered entities and related organizations, pharmaceutical/biotechnology manufacturers, and other supply chain participants to understand existing data flows and identify opportunities for increased connectivity and data sharing. CMS is also exploring options to facilitate retrospective payment exchange between manufacturers and

dispensing entities to help effectuate access to the MFP. CMS plans to release more information in advance of initial price applicability year 2026 regarding such issues related to ensuring access to the MFP, including how CMS might support and facilitate data exchange between pharmaceutical supply chain entities.

A Primary Manufacturer must ensure that pharmacies, mail order services, and other dispensers are reimbursed timely. That is, CMS requires that the MFP must be passed through to the dispensers within 14 days of the manufacturer receiving sufficient information to verify that an individual is eligible for access to the MFP. Neither Primary Manufacturers nor their contracted entities shall charge any transaction fees for the data exchanges that would be facilitated through an MTF. Regardless of whether existing processes or new processes are used to facilitate access to the MFP, manufacturers are expected to comply with existing applicable data privacy and security laws. Primary Manufacturers must work with any Secondary Manufacturer of a selected drug to determine how the MFP will be passed through in a manner that complies with applicable data privacy and security laws.

Further, CMS requires that a Primary Manufacturer submit its process for making the MFP available, including to 340B covered entities, for the selected drug in writing to CMS at least 30 days before the start of the initial price applicability year for the selected drug. CMS intends to publish these processes on the CMS IRA website. For initial price applicability year 2026, a Primary Manufacturer of a selected drug must send its process for ensuring MFP availability to CMS in writing by December 2, 2025. A Primary Manufacturer must notify CMS of any changes to its process for making the MFP available at least 30 days before the change goes into effect. CMS will monitor for compliance, and will audit as needed, to ensure that the MFP is being made available for the selected drug (see section 90.2 of this revised guidance for additional details). A Primary Manufacturer must retain for at least ten years from the date of sale any records relating to sales of the selected drug to entities that dispense the selected drug to MFP-eligible individuals, including pharmacies, mail order services, and other dispensers for units of selected drug, in alignment with the statute of limitations period under the False Claims Act.

CMS notes that the Agreement would not restrict the Primary Manufacturer or Secondary Manufacturer(s) from offering to the Part D plans a price lower than the MFP that would be passed through to the beneficiary by the dispenser. CMS reiterates that Primary Manufacturers are responsible for ensuring that the MFP is made available to pharmacies, mail order services, and other dispensers that dispense the selected drug to MFP-eligible individuals, including ensuring that MFP is available for units of the selected drug for which there is a Secondary Manufacturer. Commercial and other payers will continue to have discretion to consider Medicare payment rates among other considerations in establishing their own payment policies.

40.4.1 Nonduplication with 340B Ceiling Price

In accordance with 1193(d) of the Act and as further described in section 90.2 of this revised guidance, the Primary Manufacturer of a selected drug is not required to provide access to the MFP for a selected drug to MFP-eligible individuals who are eligible to be dispensed such selected drug at a covered entity described in section 340B(a)(4) of the PHS Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B

ceiling price (defined in section 340B(a)(1) of the PHS Act) is lower than the MFP for such selected drug.

A manufacturer that provides an MFP on a selected drug is not also required to provide a 340B discount on that same drug. That is, these price concessions are not cumulative. CMS expects that the ingredient cost component of all Part D prescriptions filled for a selected drug will be no greater than the drug's MFP, including when those prescriptions are filled at 340B covered entities and their contract pharmacies. CMS understands that 340B covered entities and their contract pharmacies currently use different inventory management processes for 340B drugs, such as separate physical drug inventories or a retrospective replenishment model. Regardless of the specific inventory management process used, the same policies regarding the MFP will apply, including that the manufacturer must provide access to the lower of the MFP or 340B ceiling price, such as through a replenished 340B inventory or an MFP refund within 14 days of determining that the selected drug was dispensed to an MFP-eligible individual.

CMS intends to work with the Health Resources and Services Administration, which administers the 340B Drug Pricing Program, to help to ensure that the MFP is made available to 340B covered entities where appropriate and that there is no duplication with the 340B ceiling price.

40.5 Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

Pursuant to CMS' statutory obligation under sections 1191(a)(4), 1196, and 1197 of the Act, CMS will establish a robust program for monitoring compliance with the Negotiation Program. After entering into an Agreement with CMS and in accordance with section 1193(a)(5) of the Act, the Primary Manufacturer must comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program. For example, CMS anticipates engaging in auditing processes to verify the accuracy and completeness of any information provided by the Primary Manufacturer under the requirements of section 1193(a)(4) of the Act. CMS also may audit any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by a Secondary Manufacturer. CMS will document all requests for information required to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. Written requests from CMS to the Primary Manufacturer will include a date by which the requested information shall be submitted to CMS. If the Primary Manufacturer fails to submit complete and accurate information to CMS by the deadline stated in a request for information, CMS will consider the Primary Manufacturer in violation of the Agreement and the Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act.

CMS will allow a Primary Manufacturer that believes in good faith that CMS has made an error in the calculation of the ceiling or the computation of how CMS will apply a single MFP across dosage forms and strengths to submit a suggestion of error for CMS' consideration. As feasible, CMS will provide information on these calculations to the Primary Manufacturer within 60 days of the Primary Manufacturer's submission of data that complies with the requirements described in section 50.1. A Primary Manufacturer will have 30 days to submit a suggestion of error and may do so by submitting the request via email to IRARebateandNegotiation@cms.hhs.gov with

the subject line "Suggestion of Error for [name of the selected drug]." This notification should include supporting information documenting why the Primary Manufacturer believes that CMS made a mathematical error in its calculations and corresponding steps that should be reviewed. CMS will review and respond within 30 days of receiving the suggestion of error from the Primary Manufacturer if feasible. The suggestion of error process does not imply that a Primary Manufacturer need not comply with Negotiation Program requirements and will not affect any timelines or requirements of the Negotiation Program.

40.6 Termination of the Agreement

In accordance with section 1193(b) of the Act, when the Primary Manufacturer enters into the Agreement described in section 40.1 of this revised guidance, the Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer considered a selected drug under section 1192(c) of the Act as described in section 70 of this revised guidance unless the Agreement is terminated sooner by the Primary Manufacturer under the conditions specified below. Accordingly, the Agreement will have an effective date as of the date the Agreement is signed by both parties (the "Effective Date"), and the term of the Agreement will be from the Effective Date of the Agreement to the earlier of the first year that begins at least 9 months after the date on which CMS determines that the selected drug is no longer a selected drug under section 1192(c) of the Act or the Agreement is terminated by either party in accordance with this section (the "Termination Date").

In accordance with section 1193(a)(5) of the Act, a Primary Manufacturer may terminate its Agreement with respect to a selected drug with respect to a price applicability period, before reaching an agreement with CMS as to the MFP for the selected drug or after such an MFP is agreed to, if the Primary Manufacturer meets certain conditions for termination consistent with the provisions in 26 U.S.C. § 5000D(c). Specifically, a Primary Manufacturer seeking to terminate its Agreement with respect to a selected drug must submit to CMS a notice of request to terminate. As noted in section 40.1, section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program and the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program. The provisions enacted at 26 U.S.C. § 5000D give the Primary Manufacturer choices with regard to the Negotiation Program. The Primary Manufacturer may participate in the Negotiation Program. The Primary Manufacturer may opt out of the Negotiation Program and pay the excise tax on the sale of the selected drug during defined periods. Alternatively, the Primary Manufacturer may opt out of the Negotiation Program and avoid the excise tax on sales of the selected drug during the period for which the manufacturer does not have applicable agreements with the Medicare and Medicaid programs and none of its drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act. Promoting continuity in the administration of the Negotiation Program warrants extending parallel options to a Primary Manufacturer with respect to potential CMP liability. A Primary Manufacturer with an Agreement with respect to the price applicability period with respect to a selected drug may opt out of the Negotiation Program and pay CMPs associated with violations of program requirements. Alternatively, a Primary Manufacturer seeking to cease participation in the Negotiation Program through the end of the price applicability period for a selected drug may avoid CMP liability by terminating its Agreement if it also ceases participation in the Medicaid Drug Rebate Program and the Medicare

Coverage Gap Discount Program and the Manufacturer Discount Program through the end of the price applicability period for the selected drug.

Thus, in accordance with section 1193(a)(5) of the Act, CMS has determined that the Primary Manufacturer's notice of termination of the Agreement must incorporate both (1) a request for termination of the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program and the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. § 5000D(c)(1)(A)(i), and (2) an attestation that through the end of the price applicability period for the selected drug, the Manufacturer (a) shall not seek to enter into any subsequent agreement with any such program and (b) shall not seek coverage for any of its drugs under the Medicare Coverage Gap Discount Program under section 1860D-14A of the Act or the Manufacturer Discount Program under section 1860D-14C of the Act, consistent with the requirements as set forth in 26 U.S.C. § 5000D(c)(1)(B). A Primary Manufacturer later seeking to re-enter any applicable agreement or obtain coverage for any of its drugs under the Medicare Coverage Gap Discount Program or the Manufacturer Discount Program would be deemed to have provided an invalid attestation that was a condition of termination, and the Agreement would once again become operative as of the date of re-entry into the applicable agreements or coverage for any of its drugs under the Medicare Coverage Gap Discount Program or the Manufacturer Discount Program. If a Primary Manufacturer terminated its Agreement prior to completing the negotiation process and agreeing to an MFP, such process will be initiated or resumed in accordance with the negotiation process described in section 60 of this revised guidance. In addition, the timing of the Primary Manufacturer's decision to resume participation in the Negotiation Program may implicate the renegotiation process beginning with 2028, for which guidance will be forthcoming for future years of the Negotiation Program.

If the conditions for termination of the Agreement for the Negotiation Program described above are met, CMS will terminate such Agreement effective on the first date on which the notices of termination for all applicable agreements have been received and none of the drugs of the Primary Manufacturer are covered by an agreement under the Medicare Coverage Gap Discount Program or the Manufacturer Discount Program. As is noted above, section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program and the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program. If a Primary Manufacturer determines after executing its Agreement that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice that complies with the requirements in this section 40.6, CMS will find good cause to terminate the Primary Manufacturer's agreement(s) under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable, pursuant to section 1860D-14A(b)(4)(B)(i) and section 1860D-14C(b)(4)(B)(i) of the Act to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under section 1860D-14A or section 1860D-14C and thus facilitate an expedited Termination Date.

Moreover, consistent with the process described in Section 40.1 above, if a Primary Manufacturer has determined it is unwilling to continue its participation in the Negotiation Program and provides a termination notice that complies with the requirements in this section

40.6, CMS shall, upon written request from such Primary Manufacturer, provide a hearing concerning its termination request for its applicable agreements under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program, as applicable. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the Primary Manufacturer to rescind its termination request.

Notwithstanding any termination of the Agreement, the MFP shall continue to apply for any selected drugs that were dispensed prior to the Termination Date. Also, notwithstanding the termination of the Agreement, any confidentiality, record retention, and/or data requirements and any requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities shall continue to apply.

40.7 Other Provisions in the Agreement

Additional terms in the Agreement set forth general provisions in accordance with requirements determined by CMS to be necessary for purposes of administering or monitoring compliance with the Negotiation Program. For example, any notice required to be given by the manufacturer or CMS must be sent in writing via email to CMS- and manufacturer-designated email addresses. CMS retains the authority to amend the Agreement to reflect changes in law, regulation, or guidance, and, when possible, CMS will give the Manufacturer at least 60-day notice of any change to the Agreement.

In accordance with section 1193(a)(5) of the Act, if, after entering in an Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs / BLAs of the selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Agreement, including the requirement to provide access to the MFP, associated with the transferred NDAs / BLAs unless and until the Primary Manufacturer transfers all the NDAs / BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer. Those steps must be evidenced by a novation to the transferring Primary Manufacturer's original Agreement for the Negotiation Program. The transferring Primary Manufacturer remains responsible for any outstanding Negotiation Program rebate liabilities related to the biosimilar delay provision under section 1192(f) of the Act unless and until such liabilities are transferred to the acquiring entity as the new Primary Manufacturer. The transferring Primary Manufacturer shall provide CMS at least 30 calendar days written notice before the effective date of any such transfer and, if applicable, any novation.

If the Primary Manufacturer of a selected drug transfers all NDAs / BLAs of the selected drug pursuant to the preceding paragraph, such that an acquiring entity assumes responsibility as the new Primary Manufacturer of the selected drug for purposes of the Negotiation Program, CMS recognizes that this transfer of ownership could affect the Primary Manufacturer's potential excise tax liability as well as the impact on the Primary Manufacturer of the statutory suspension

of excise tax provisions and the termination process as described in section 40.6 of this revised guidance. CMS recognizes that whether this transfer of ownership would have these impacts would depend on whether the transfer of the NDAs / BLAs was made to an entity that is not a related party (e.g., not treated as part of the same employer under subsections (a) and (b) of section 52 of the Internal Revenue Code of 1986) and complied with relevant principles of tax law.

If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if the invalid or unenforceable provision(s) were eliminated, and without any effect on any other provisions.

50. Negotiation Factors

In accordance with sections 1193(a)(4) and 1194(b)(2)(A) of the Act, the Primary Manufacturer of a selected drug that has chosen to sign the Agreement must submit, in a form and manner specified by CMS, information on the non-FAMP for the selected drug (described in section 50.1.1 of this revised guidance). The Primary Manufacturer must also submit information on certain factors (described in section 1194(e)(1) of the Act and described further in section 50.1 of this revised guidance). The Primary Manufacturer will be responsible for aggregating and reporting information from any applicable Secondary Manufacturer(s). In addition, the statute prescribes that CMS also consider available evidence about therapeutic alternatives to the selected drug(s) (described in section 1194(e)(2) of the Act and described further in section 50.2 of this revised guidance).

While the statute requires that CMS consider manufacturer-specific data for the factors described at section 1194(e)(1) of the Act, the statute does not specify what sources CMS must use for the factors described at section 1194(e)(2) regarding therapeutic alternatives to a selected drug. CMS will consider evidence about therapeutic alternatives relevant to the factors described in section 1194(e)(2) of the Act submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties. CMS believes that by allowing any interested party to submit data, CMS will be best positioned to identify all available, relevant evidence for the factors described at section 1194(e)(2).

CMS published the Negotiation Data Elements ICR in the Federal Register on March 21, 2023. The Negotiation Data Elements ICR describes how CMS will collect the data outlined in sections 1193(a)(4)(A), 1194(e)(1), and 1194(e)(2) of the Act. This ICR includes instructions on how Primary Manufacturers and members of the public may submit relevant data. The comment period for the Negotiation Data Elements ICR closed on May 22, 2023. CMS is releasing a revised version of the Negotiation Data Elements ICR on June 30, 2023, and the 30-day comment period will close on July 31, 2023.

The definitions that CMS is adopting for the purposes of describing the data to be collected for use in the Negotiation Program under sections 1193(a)(4)(A) and 1194(e)(1) of the Act are specified in Appendix C of this revised guidance.

In accordance with sections 1191(d)(5)(A), 1194(b)(2)(A), and 1193(a)(4)(B) of the Act, the data described in sections 50.1 and 50.2 of this revised guidance for drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023. CMS' determination to

require public submission on the same date as manufacturer submission (i.e., October 2, 2023) serves to enable CMS to consider all submitted evidence in totality and meet the statutory deadline for the initial offer, pursuant to general program administration authority.

50.1 Manufacturer-Specific Data

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers, as described in section 60 of this revised guidance. These factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Submission of these data by the Primary Manufacturer is required if an Agreement is signed; details related to the submission process are described in section 40.2 of this revised guidance.

These data include the following and are required to be reported by the Primary Manufacturer to CMS by October 2, 2023:

1. Research and development (R&D) costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
3. Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and
5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s).

The Primary Manufacturer should submit information in the CMS HPMS for the NDC-11s of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to section 40.2 of this revised guidance. As noted above, CMS requires the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-FAMP, current unit costs of production and distribution, and certain data pertaining to market data and revenue and sales volume data for the selected drug.

Please see Appendix C of this revised guidance for a list of definitions that apply for purposes of describing these data to be collected for use in the Negotiation Program.

50.1.1 Non-FAMP Data

The Primary Manufacturer must submit data on non-FAMP for the selected drug for the Primary Manufacturer and any Secondary Manufacturer(s), as required under section 1193(a)(4)(A) of the Act. CMS will be collecting these data through the Negotiation Data Elements ICR described above. Specifically, for initial price applicability year 2026, the Primary Manufacturer must submit the non-FAMP, unit type, and total unit volume for each NDC-11 of the selected drug for the four quarters of calendar year 2021, or in the case that there is not an average non-FAMP price available for such drug for 2021, the non-FAMP, unit type, and total unit volume for each

NDC-11 of the selected drug for the four quarters of the first full calendar year following market entry of such drug. For purposes of determining the applicable year, CMS will consider the average non-FAMP price to be available for a selected drug for calendar year 2021 if the Primary Manufacturer reports at least one quarter of non-FAMP data for at least one NDC-11 of the selected drug in calendar year 2021. As described in Appendix C, when there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) for a given NDC-11 of such drug, the non-FAMP reported by the manufacturer to CMS for that calendar quarter should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price as described in the Department of Veterans Affairs' (VA) 2023 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585. Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS. The use of these data to calculate the ceiling for the MFP is further described in section 60.2 of this revised guidance. Details on how CMS defines the parameters of the non-FAMP data collection are included in Appendix C of this revised guidance and are also included in the Negotiation Data Elements ICR.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

As noted above, section 1194(e)(2) of the Act directs CMS to consider evidence about alternative treatments to the selected drug, as available, including:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, herein referred to as "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Section 1194(e)(2) of the Act additionally requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Information submitted by members of the public, including manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties, or other information found by CMS that treats extending the life of individuals in these populations as of lower value will not be used in the Negotiation Program.[57]

[57] Some uses of QALY treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. CMS will not use any QALY in the Negotiation Program.

CMS will review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the measure used is permitted in accordance with section 1194(e)(2), as well as with section 1182(e) of Title XI of the Act. CMS may use content in a study that uses a cost effectiveness-measure if it determines that the cost-effectiveness measure used is permitted in accordance with the law and does not treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. In instances where some, but not all, content in a study is excluded (e.g., QALYs), CMS may still consider content that is relevant and allowable (e.g., clinical effectiveness, risks, harms) under section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act. CMS requires respondents submitting information to indicate whether their submission contains information from studies that use measures that treat extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. CMS also requests that respondents submitting information under 1194(e)(2) provide a short description of any cost-effectiveness measures included in the research they are submitting, and how they believe the data avoids treating extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

The Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties, may submit information on selected drugs and their therapeutic alternatives (specifically pharmaceutical therapeutic alternatives, as described in detail in section 60.3.1 of this revised guidance), including information on whether the selected drug represents a therapeutic advance over its therapeutic alternative(s), prescribing information for the selected drug and its therapeutic alternative(s), comparative effectiveness data for the selected drug and its therapeutic alternative(s), information about the impact of the selected drug and its therapeutic alternative(s) on specific populations, information about patient experience, and/or information on whether the selected drug addresses unmet medical need, as described in section 1194(e)(2) of the Act. Outcomes such as changes to productivity, independence, and quality of life will also be considered when these outcomes correspond with a direct impact on the individuals taking the selected drug or therapeutic alternative and are appropriately measurable and quantifiable.

CMS will additionally review existing literature and real-world evidence, conduct internal analytics, and consult subject matter and clinical experts on these topics (described in section 60.3.1 of this revised guidance) when considering available evidence about alternative treatments to the selected drug. When reviewing the literature from the public and manufacturer submissions as well as literature from CMS' review, CMS will consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. CMS will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (i.e., has sufficient sample size) to answer the primary question

of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses.

CMS will consider research and real-world evidence relating to Medicare populations, including on individuals with disabilities, patients with end-stage renal disease (ESRD), and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, CMS will prioritize research specifically designed to focus on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus.

All information on the factors described in section 1194(e)(2) of the Act related to drugs selected for initial price applicability year 2026 must be submitted to CMS by October 2, 2023.

Please see Appendix C of this revised guidance for a list of definitions that CMS adopted for the purposes of describing these data to be collected for use in the Negotiation Program.

60. Negotiation Process

In accordance with section 1194(b)(1) of the Act, CMS will develop and use a consistent methodology and process for negotiation with the aim of achieving agreement on "the lowest maximum fair price for each selected drug." This section 60 describes the negotiation process, including the development of the written initial offer, the process for making such offer and providing a concise justification to the Primary Manufacturer of a selected drug, the process and requirements for accepting an offer or providing a counteroffer, the potential for up to three negotiation meetings between CMS and the Primary Manufacturer, the conclusion of negotiation, the publication of the MFP, and explanation of the MFP.

60.1 Establishment of a Single MFP for Negotiation Purposes

In accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b), as applicable, for such drug and year. CMS interprets this language to refer to negotiation of a single price for a selected drug with respect to its price applicability period. Accordingly, CMS will identify a single price for use at each step in the negotiation process described in this section 60, meaning each offer and counteroffer, described in section 60.4 of this revised guidance, will include a single price, even for a selected drug with multiple dosage forms and strengths. Once the MFP has been agreed upon, section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply the MFP across different dosage forms and strengths of a selected drug.

For the purposes of determining a single price included in an initial offer (including evaluating clinical benefit compared to the therapeutic alternative(s), as described in section 60.3 of this revised guidance) and conducting the negotiation, CMS will base the single price on the cost of the selected drug per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection – or per volume or weight-based metric), weighted across dosage forms and strengths. This approach of negotiating a single price across all dosage forms and strengths aligns with the statutory requirement to negotiate an MFP for a selected drug. CMS believes this will also allow for a more direct comparison with the therapeutic alternative(s), which might have different

dosage forms, strengths, and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) than the selected drug.

Section 60.5 of this revised guidance describes the methodology CMS will use to translate the MFP once finalized (which, per above, will be an average price per 30-day equivalent supply for the selected drug) back into per unit (e.g., tablet) prices at the dosage form and strength level for the purposes of publishing per-unit MFPs for the different dosage forms and strengths of the selected drug at the NDC- 9 and NDC-11 levels, as contemplated under section 1196(a)(2). In addition to the description of that methodology included in this revised guidance, CMS will share the inputs behind that methodology specific to the selected drug with the Primary Manufacturer of the selected drug during the negotiation period such that the Primary Manufacturer will have visibility into the implied unit prices based on the MFP for each dosage form and strength throughout the negotiation process (i.e., any offer or counteroffer that identifies a single price would be clearly translatable to per unit prices at the dosage form and strength level). Please see section 60.5 of this revised guidance for details.

60.2 Limitations on Offer Amount

In accordance with section 1194(b)(2)(F)(i) of the Act, in negotiating the MFP of a selected drug, with respect to initial price applicability year 2026, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. This section 60.2 of this revised guidance provides details on the determination of the ceiling for the MFP and comparison of the ceiling to the MFP.

60.2.1 Determination of the Ceiling for the MFP

In accordance with section 1194(c) of the Act, for initial price applicability year 2026, the ceiling for the MFP for a selected drug shall not exceed the lower of the following:

- As described in section 60.2.2 of this revised guidance, an amount equal to the sum of the plan-specific enrollment weighted amounts; or
- As described in section 60.2.3 of this revised guidance, an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP as defined in section 1194(c)(6) of the Act for such drug for calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.[58]

CMS interprets the language in section 1194(c)(1)(A) of the Act to mean it should calculate a single amount across all dosage forms and strengths of the selected drug for the sum of the plan-specific enrollment weighted amounts and for the applicable percent of the average non-FAMP in order to determine which one is lower and will serve as the ceiling for the MFP. To determine whether the sum of the plan-specific enrollment weighted amounts or the applicable percent of the average non-FAMP will be used to calculate the ceiling for the MFP, CMS will aggregate the

[58] The September 2021 CPI-U, not seasonally unadjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.202 percent. Data retrieved from https://www.bls.gov/cpi/data.htm on May 16, 2023.

amounts determined for each NDC-11 for the selected drug to calculate a single amount – separately for each methodology – across dosage forms, strengths, and package sizes of the selected drug. These amounts can then be directly compared, and the ceiling for the single MFP of the selected drug (including all dosage forms and strengths) will be the lower amount.

CMS will calculate a single ceiling per 30-day equivalent supply (please see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology) across all dosage forms and strengths of the selected drug. Using the price per 30-day equivalent supply to calculate this amount facilitates aggregation across dosage forms and strengths of a selected drug where units (e.g., mg versus ml) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ. Sections 60.2.2 and 60.2.3 of this revised guidance describe the process for calculating the sum of the plan-specific enrollment weighted amounts and for calculating the applicable percent of the average non-FAMP, respectively, and section 60.2.4 describes the selection of the ceiling for the single MFP.

For new NDCs included in the definition of the selected drug that are marketed before the ceiling is calculated, the new NDC will be included in the ceiling calculation (as described in this section) provided that CMS receives non-FAMP price data for at least one calendar quarter in calendar year 2021 (or for the first full calendar year following market entry) and observes PDE days supply, PDE quantity dispensed, and PDE gross expenditures for at least one quarter in calendar year 2022, and DIR amounts for calendar year 2022.

CMS will not include a new NDC in the ceiling calculation if any of the above PDE elements do not have at least one calendar quarter of data in calendar year 2022 or if there are no DIR amounts for calendar year 2022 or the Primary Manufacturer did not submit non-FAMP price data for at least one quarter of calendar year 2021 (or for the first full calendar year following market entry).

60.2.2 Sum of the Plan-Specific Enrollment Weighted Amounts

In accordance with section 1194(c)(1)(B)(i) of the Act, CMS will calculate for a selected drug an amount equal to the sum of the plan-specific enrollment weighted amounts determined using the methodology described in section 1194(c)(2) of the Act. Plan sponsors report Part D PDE data to CMS at the NDC-11 level. Sponsors also report Direct and Indirect Remuneration (DIR) data to CMS at the NDC-11 level in the annual Detailed DIR Report. CMS will use these reported data for plan year 2022, which is the most recent year for which data will be available, for the purpose of determining the sum of the plan-specific enrollment weighted amounts for a selected drug for initial price applicability year 2026.

CMS will include all Part D plans that have PDE data for dosage forms and strengths of the selected drug in this calculation. Because CMS will have no PDE data for Part D plans in the following circumstances, such Part D plans will, by definition, be excluded from the calculation of the plan-specific enrollment weighted amounts: (1) plans that have no utilization for the selected drug and (2) plans that have no enrollment for 2022.[59] CMS will also exclude any PDE

[59] CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.

records for the selected drug for which the total gross covered prescription drug cost is equal to $0.

CMS will calculate the sum of the plan-specific enrollment weighted amounts in two stages. First, CMS will calculate the sum of the plan-specific enrollment weighted amounts for each NDC-9 associated with NDC-11s included on the list of NDC-11s of the selected drug in the CMS HPMS (see section 40.2 of this revised guidance). Second, CMS will calculate the sum of the plan-specific enrollment weighted amounts across these NDC-9s. The amounts calculated at each stage are for a 30-day equivalent supply (see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology).

To determine the sum of the plan-specific enrollment weighted amounts for each NDC-9 and across all NDC-9s of the selected drug, CMS will conduct the following steps.

Steps 1 through 8 will result in the sum of the plan-specific enrollment weighted amounts for each NDC-9 of the selected drug:

1. For each Part D plan, CMS will identify the PDE data for the selected drug for 2022 (that is, PDE records with dates of service during the period beginning on January 1, 2022 and ending on December 31, 2022).
2. For each Part D plan and each NDC-9, CMS will separately sum the negotiated price amounts (as defined in 42 C.F.R. § 423.100), the estimated rebate at point-of-sale amounts (ERPOSA), and units dispensed.
3. For each Part D plan and each NDC-9, CMS will sum the total DIR amounts found in the 2022 Detailed DIR Report and subtract the total ERPOSA calculated in step 2 to avoid double counting price concessions applied at the point of sale.
4. For each Part D plan and each NDC-9, CMS will subtract the total DIR minus ERPOSA amount calculated in step 3 from the total negotiated price amounts calculated in step 2 and then divide by the total units dispensed also determined in step 2. This calculation results in the NDC-9 price per unit, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan.
5. Separately, CMS will identify the total number of individuals enrolled in all Part D plans in December 2022 and the total number of individuals enrolled in each Part D plan in that same month.[60] The Part D plans included in both calculations of step 5 will be restricted to Part D plans with at least one PDE record for the selected drug in calendar year 2022.
6. For each Part D plan and each NDC-9, CMS will divide the total number of Part D beneficiaries enrolled in the Part D plan during December 2022 as identified in step 5 by the total number of individuals enrolled in all Part D plans in December 2022 also as identified in step 5, and multiply this quotient by the price per unit, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan, calculated in step 4, to arrive at the plan-specific enrollment weighted amount.
7. For each NDC-9, CMS will then sum the amounts calculated in step 6 across all Part D plans to calculate the sum of the plan-specific enrollment weighted amounts.

[60] CMS conducted an analysis of monthly Part D plan enrollment changes during 2022 and determined that monthly enrollment changes were the lowest from November to December, so CMS chose December as the most stable month to identify enrollment. The choice of one month to identify enrollment also allows the weights calculated in step 6 to sum to one.

8. For each NDC-9, CMS will then multiply the sum of the plan-specific enrollment weighted amounts calculated in step 7, which are a per unit price, by the NDC-9 average number of units per 30-day equivalent supply calculated from PDE data for 2022 to yield the price of a 30-day equivalent supply.

Steps 9 through 10 result in the sum of the plan-specific enrollment weighted amounts across all NDC-9s of the selected drug:

9. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s, both calculated from 2022 PDE data, and multiply this quotient by the sum of the plan-specific enrollment weighted amounts for a 30-day equivalent supply as calculated in step 8.
10. CMS will then sum amounts calculated in step 9 across all NDC-9s to generate the sum of the plan-specific enrollment weighted amounts for the selected drug for a 30-day equivalent supply.

60.2.3 Average Non-Federal Average Manufacturer Price

In accordance with section 1194(c)(1)(C)(i) of the Act, for initial price applicability year 2026, CMS will calculate an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, CMS will use the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) (CPI-U) from September 2021 (or December of such first full year following the market entry), as applicable, to September 2022.[61]

For this calculation, CMS will use the non-FAMP price and unit volume data, as provided by the Primary Manufacturer, for each NDC-11 included on the list of NDC-11s of the selected drug in the CMS HPMS (see section 40.2 of this revised guidance), for each quarter of calendar year 2021 that is submitted to CMS by the Primary Manufacturer pursuant to section 1193(a)(4)(A) of the Act (as described in section 50.1 of this revised guidance) to calculate an annual average non-FAMP per unit. CMS will use 2022 PDE quantity dispensed and days supply data submitted to CMS at the NDC-11 level by Part D plan sponsors for the following: to calculate an annual average non-FAMP per unit for each NDC-9 of the selected drug, to calculate the annual average non-FAMP per 30-day equivalent supply for each NDC-9 of the selected drug, and to calculate the annual average non-FAMP per 30-day equivalent supply for the selected drug. In order to directly compare the amount calculated based on the applicable percent of average non-FAMP and the amount calculated based on the sum of the plan-specific enrollment weighted amounts (as described in section 60.2.2 above), CMS will base the average non-FAMP calculations on a 30-day equivalent supply and use the same 2022 PDE data for weighting both the sum of the plan-specific enrollment weighted amounts and the average non-FAMP across dosage forms and strengths to determine which amount is lower.

CMS will calculate the applicable percent of the average non-FAMP in two stages to determine the ceiling for the MFP. First, CMS will calculate the applicable percent of the average non-FAMP for each NDC-9 of the selected drug. Second, CMS will calculate the applicable percent

[61] The September 2021 CPI-U, not seasonally adjusted, was 274.310; the September 2022 CPI-U, not seasonally adjusted, was 296.808. The percentage increase was 8.202 percent. Data retrieved from https://www.bls.gov/cpi/data.htm on May 16, 2023.

of the average non-FAMP across NDC-9s of the selected drug. The amounts calculated in each stage are for a 30-day equivalent supply (see 42 C.F.R. § 423.104(d)(2)(iv)(A)(2) for details on 30-day equivalent supply methodology).

To determine the applicable percent of the average non-FAMP for each NDC-9 and across all NDC-9s of the selected drug, CMS will conduct the following steps.

Steps 1 through 9 will result in the average non-FAMP, adjusted for inflation and with the applicable percent applied, for each NDC-9 of the selected drug:

1. To calculate an average non-FAMP that is comparable to the sum of the plan-specific enrollment weighted amounts described in section 60.2.2 of this revised guidance, CMS will compare the non-FAMP unit type (e.g., tablet) to the PDE units (i.e., each, milliliter, and grams). In instances where the units are different, CMS will convert the non-FAMP unit type to the PDE units so that the two amounts (average non-FAMP and sum of the plan-specific enrollment weighted amounts) represent the same quantity of the selected drug.[62]
2. For each NDC-11 and for each quarter during calendar year 2021, CMS will calculate the non-FAMP per unit by dividing the non-FAMP per package by the total number of units per package.
    - Note: If the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 50.1.1 of this revised guidance), CMS will use the non-FAMP for the quarters of the first full calendar year following the market entry for such drug.
3. For each NDC-11 and for each quarter during calendar year 2021, CMS will divide the total unit volume (calculated as the product of the total number of packages sold by the number of units per package from manufacturer-reported non-FAMP data) in that quarter by the total unit volume across all four quarters during calendar year 2021 (also from manufacturer reported non-FAMP data), and multiply this quotient by the non-FAMP per unit calculated in step 2.
    - Note: If the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021 (as described in section 50.1.1 of this revised guidance), CMS will use the non-FAMP and total unit volumes for the quarters of the first full calendar year following the market entry for such drug.
4. For each NDC-11, CMS will sum the amounts calculated in step 3 across quarters to calculate the average non-FAMP per unit for that NDC-11 for the calendar year CMS believes steps 3 and 4 are necessary to account for non-FAMP unit volume fluctuations that may occur across quarters.
5. For each NDC-11, CMS will divide the total quantity dispensed for that NDC-11 by the total quantity dispensed for all applicable NDC-11s of the same NDC-9 (both calculated from 2022 PDE data) and multiply this quotient by the average non-FAMP per unit for the calendar year calculated in step 4.
6. For each NDC-9, CMS will sum the amounts calculated in step 5 to calculate the average non-FAMP per unit for that NDC-9 for the calendar year. CMS believes steps 5 and 6 are

[62] PDE units are industry standard National Council for Prescription Drug (NCPDP) defined values of each, milliliter, and grams. See: https://standards ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

necessary to account for fluctuations in quantity dispensed that may occur across NDC-11s of an NDC-9 in the Medicare Part D population.

7. For each NDC-9, CMS will then increase the average non-FAMP per unit for calendar year 2021 calculated in step 6 by the percentage increase in CPI-U (all items; United States city average) from September 2021 until September 2022 as specified in section 1194(c)(1)(C)(i) of the Act.
    - Note: For initial price applicability year 2026, if the non-FAMP is missing for all NDC-11s of the selected drug for calendar year 2021(as described in section 50.1.1 of this revised guidance), and the non-FAMP is based on data from the first full calendar year following the market entry of the such drug, which can only be calendar year 2022, CMS will not apply the CPI-U adjustment.
8. For each NDC-9, after CMS has calculated the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable, CMS will then apply the applicable percent specified in section 1194(c)(3) of the Act for the monopoly type determined for the selected drug based on its initial approval date (described in section 30.1 of this revised guidance). Applying the applicable percent here, in step 8, results in the same step 11 amount as would result if CMS were to apply the applicable percent to the average non-FAMP per 30-day equivalent supply for the selected drug in step 11. The definition of each monopoly type and the applicable percentage are described below for initial price applicability year 2026. CMS notes that the "extended-monopoly" type is not discussed below because the definition of extended-monopoly drug under section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an Agreement with CMS with respect to an initial price applicability year that is before 2030. CMS interprets this to mean that no selected drug will be considered an extended-monopoly drug for purposes of calculating the ceiling prior to initial price applicability year 2030.

Figure 2: Monopoly Types and Applicable Percentage for Initial Price Applicability Year 2026

Monopoly Type	Definition	Applicable Percentage	Note
Short-monopoly drugs and vaccines (section 1194(c)(3)(A) of the Act)[63]	For initial price applicability year 2026, a selected drug that is not a long-monopoly drug or a selected drug that is a vaccine licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	75%	The first approval date, under section 505(c) of the FD&C Act, associated with the initial FDA application number for the active moiety (or fixed combination drug) must be after January 1, 2010 and before September 1, 2016. The first licensure date, under section 351(a) of the PHS Act, associated with the initial FDA application number for the active ingredient (or fixed combination drug) must be after January 1, 2010 and before September 1, 2012.
Long-monopoly drug (section 1194(c)(5)(A) of the Act)	A selected drug for which at least 16 years have elapsed since the date of approval under section 505(c) of the FD&C Act or since the date of licensure under section 351(a) of the PHS Act, as applicable. The term 'long-monopoly drug' does not include a vaccine that is licensed under section 351(a) of the PHS Act and marketed pursuant to that section.	40%	The first approval date under section 505(c) of the FD&C Act or the first licensure date under section 351(a) of the PHS Act, as applicable, associated with the initial FDA application number for the active moiety / active ingredient (or fixed combination drug) must be on or before January 1, 2010.

9. For each NDC-9, CMS will then multiply the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied as calculated in step 8 by the quotient of the total quantity dispensed divided by the total 30-day equivalent supply (i.e., this quotient represents the average units per 30-day supply equivalent for that NDC-9) calculated from 2022 PDE data to determine the

[63] Because the definition of extended-monopoly drug at section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a manufacturer has entered into an agreement with CMS with respect to an initial price applicability year before 2030, for initial price applicability year 2026, any drug, biological product, or vaccine that is not considered a long-monopoly drug will be considered a short monopoly drug.

average non-FAMP for a 30-day equivalent supply. As described above in section 60.2.1 of this revised guidance, CMS believes calculating the average non-FAMP for a 30-day equivalent supply is necessary to account for different units and treatment regimens across dosage forms and strengths.

Steps 10 and 11 will calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with applicable percent applied, across all NDC-9s of the selected drug:

10. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s of the selected drug, both calculated from 2022 PDE data, and multiply this quotient by the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied, calculated in step 9.
11. CMS will then sum amounts calculated in step 10 across all NDC-9s of the selected drug to calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable, and with the applicable percent applied, for the selected drug.

60.2.4 Selection and Application of the Ceiling for the MFP

CMS will compare the values calculated in step 10 of section 60.2.2 of this revised guidance (sum of the plan-specific enrollment weighted amounts) and step 11 of section 60.2.3 of this revised guidance (applicable percent of the average non-FAMP) and select the lower value as the ceiling for the selected drug. Once CMS has identified whether the ceiling would be determined by the sum of the plan-specific enrollment weighted amounts or the applicable percent of the average non-FAMP, CMS will ensure that the MFP per 30-day equivalent supply, as negotiated through the process described in sections 60.3 and 60.4 of this revised guidance, is no greater than the lower ceiling.

60.3 Methodology for Developing an Initial Offer

Section 1194(e) of the Act directs CMS to consider certain factors related to manufacturer-specific data and available evidence about therapeutic alternative(s) as the basis for determining offers and counteroffers in the negotiation process. The statute requires CMS to provide the manufacturer of a selected drug with an initial offer and a concise justification based on the factors described in section 1194(e) that were used in developing the offer; however, CMS has the discretion to determine how and to what degree each factor should be considered.

As discussed in greater detail below, consistent with section 1194(e) of the Act, for the purposes of determining an initial offer, CMS will (1) identify therapeutic alternative(s), if any, for the selected drug as described in section 60.3.1 of this revised guidance; (2) use the Part D net price for the therapeutic alternative(s) that is covered under Part D and/or the Average Sales Price (ASP) for the therapeutic alternative(s) that is covered under Part B to determine a starting point for developing an initial offer as described in section 60.3.2 of this revised guidance; (3) evaluate the clinical benefit of the selected drug (including compared to its therapeutic alternative(s)) for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2) of the Act, including whether the selected drug meets an unmet medical need and the selected drug's impact on specific populations, as described in section 60.3.3 of this revised

guidance (resulting in the "preliminary price"); and (4) further adjust the preliminary price by the negotiation factors outlined in section 1194(e)(1) of the Act (described in section 60.3.4 of this revised guidance) to determine the initial offer price.

Pursuant to section 1194(b)(2)(F) of the Act, CMS will not make any offers or accept any counteroffers for the MFP that are above the statutorily defined ceiling.

60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication

For initial price applicability year 2026, CMS will identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act for a selected drug, using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. CMS will consider off-label use when identifying indications if such use is included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia.[64]

For each indication of the selected drug, CMS will next identify a pharmaceutical therapeutic alternative(s). CMS considered evaluating non-pharmaceutical therapeutic alternatives; however, for initial price applicability year 2026, CMS will only consider therapeutic alternatives that are drugs or biologics covered under Part D or Part B. CMS believes that pharmaceutical therapeutic alternatives will be the most analogous alternatives to the selected drug when considering treatment effect and price differentials. For purposes of this revised guidance, the term "therapeutic alternative" may refer to one or more therapeutic alternative(s) or a subset of the most clinically comparable therapeutic alternatives.

To identify potential therapeutic alternatives for the indications of a selected drug, CMS will use data submitted by the Primary Manufacturer and the public, FDA-approved indications, drug classification systems commonly used in the public and commercial sector for formulary development, indications included in CMS-approved Part D compendia, widely accepted clinical guidelines, the CMS-led literature review, drug or drug class reviews, and peer-reviewed studies. In addition to brand name drugs and biologics, CMS will consider generic drugs and biosimilars when identifying a therapeutic alternative(s) to a selected drug. CMS will consider off-label use for therapeutic alternatives when identifying indications if such use is included in nationally recognized, evidence-based guidelines and recognized in CMS-approved Part D compendia.

CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on the subset of therapeutic alternatives that are most clinically comparable to the selected drug for the purpose of developing the initial offer. CMS may consult with FDA to obtain information regarding other approved therapies for the same indication and may also consult with clinicians, patients or patient organizations, and/or academic experts, to ensure that appropriate therapeutic alternatives are identified. If a therapeutic alternative has not yet been incorporated into nationally recognized, evidence-based guidelines, CMS will consider clinical evidence available

[64] CMS-approved Part D compendia are described in Chapter 6, § 10.6 of the Prescription Drug Benefit Manual.

through a literature search and information submitted by the Primary Manufacturer and the public to inform the selection of a therapeutic alternative(s). In all cases, CMS will select therapeutic alternatives based on clinical appropriateness.

60.3.2 Developing a Starting Point for the Initial Offer

CMS considered several options for what price should be used as the starting point for developing the initial offer. Options considered included the use of the Part D net price(s) and/or the ASP(s) of therapeutic alternative(s), if any, to the selected drug, the unit cost of production and distribution for the selected drug, the ceiling for the selected drug (as described in section 60.2 of this revised guidance), a domestic reference price for the selected drug (e.g., the Federal Supply Schedule[65] (FSS) price), or a "fair profit" price for the selected drug based on whether R&D costs have been recouped and margin on unit cost of production and distribution. Under any of these options, the initial offer and final MFP would be capped at the statutory ceiling.

After considering these options and in accordance with section 1194(e)(2)(A) of the Act which directs CMS to consider the cost of therapeutic alternative(s), CMS will use the Part D net price(s) ("net price(s)") and/or ASP(s) of the therapeutic alternative(s) (or a subset of the most clinically comparable therapeutic alternatives) for the selected drug, as applicable, as the starting point for developing the initial offer unless this net price or ASP is greater than the statutory ceiling (described in section 60.2 of this revised guidance), and will then consider adjustments based on section 1194(e)(2) data and manufacturer-submitted data per section 1194(e)(1). CMS intends to identify the price of each therapeutic alternative that is covered under Part D net of all price concessions received by any Part D plan or pharmacy benefit manager on behalf of the Part D plan by using PDE data and detailed DIR report data. In taking this approach, CMS acknowledges that the therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit, however, using net prices and ASPs of therapeutic alternatives enables CMS to start developing the initial offer within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition. By using the price(s) of the selected drug's therapeutic alternative(s), CMS will be able to focus the initial offer on clinical benefit by adjusting this starting point relative to whether the selected drug offers more, less, or similar clinical benefit compared to its therapeutic alternative(s). The other options considered do not provide a starting point that reflects the cost of therapeutic alternatives in the current market, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries relative to the other drug(s) available to treat the patient's disease or condition.

When comparing prices of therapeutic alternatives for purposes of informing a starting point for the initial offer, CMS may use an alternative methodology for calculating a 30-day equivalent supply as appropriate. For example, because Part B claims data do not contain a "days' supply" field similar to PDE data, CMS may use an alternative methodology to calculate the price per 30-day equivalent supply for therapeutic alternatives covered under Part B.

[65] The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/about-gsa-schedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20government.

If there is one therapeutic alternative for the selected drug, CMS will use the net price or ASP, as applicable, of the therapeutic alternative (if it is lower than the ceiling) as the starting point to develop CMS' initial offer for the MFP. If there are multiple therapeutic alternatives, CMS will consider the range of net prices and/or ASPs, including the prices of generic and biosimilar therapeutic alternatives, as well as the utilization of each therapeutic alternative relative to the selected drug, to determine the starting point within that range. If the selected drug has no therapeutic alternative, if the prices of the therapeutic alternatives identified are above the statutory ceiling for the MFP (as described in section 60.2 of this revised guidance), or if there is a single therapeutic alternative with a price above the statutory ceiling for the MFP, then CMS will determine the starting point for the initial offer based on the FSS or "Big Four Agency"[66] price ("Big Four price"). If the FSS and Big Four prices are above the statutory ceiling, then CMS will use the statutory ceiling as the starting point for the initial offer. In all cases, this starting point will be subject to adjustments as described further below.

60.3.3 Adjusting the Starting Point Based on Clinical Benefit

To evaluate the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), as applicable, CMS will broadly evaluate the body of clinical evidence, including data received from the public and manufacturers as described in section 50.2 of this revised guidance, and data identified through a CMS-led literature review. CMS may also analyze Medicare claims or other datasets for utilization patterns of the selected drug versus its therapeutic alternative(s), clinical data, or other information relevant to the selected drug and its therapeutic alternative(s) and may consult with clinicians, patients or patient organizations, academic experts, and/or the FDA. As described in section 60.4 of this revised guidance, CMS will provide additional engagement opportunities for interested parties—specifically, meetings with manufacturers and patient-focused listening sessions—after the October 2, 2023 deadline for submission of section 1194(e)(2) data (further described in section 60.4 of this revised guidance).

This approach provides a pathway for CMS to consider the multitude of information expected from public input, including but not limited to peer-reviewed research, expert reports or whitepapers, clinician expertise, real-world evidence, and patient experience. This approach also provides flexibility for CMS to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

Once the starting point for the initial offer has been established and evidence on clinical benefit has been considered, CMS will adjust the starting point for the initial offer based on the review of the clinical benefit. CMS will not, per section 1194(e)(2) of the Act, use evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual

[66] The Big Four price is the maximum price a drug manufacturer is allowed to charge the "Big Four" federal agencies, which are the Department of Veterans Affairs (VA), Department of Defense (DoD), the Public Health Service, and the Coast Guard. See section 8126 of title 38 of the U.S. Code. See: https://www.cbo.gov/publication/57007.

who is younger, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs. CMS considered employing both a qualitative approach (e.g., adjusting the starting point upward or downward relative to the clinical benefit offered by the selected drug compared to its therapeutic alternatives) and a more thoroughly pre-specified quantitative approach. CMS will use a qualitative approach to preserve flexibility in negotiation, including the ability to consider nuanced differences between different drugs, for example interactions with other treatments commonly prescribed simultaneously for a condition or disease, and other factors that might not be captured in a more thoroughly pre-specified quantitative approach.

60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

To consider comparative effectiveness between a selected drug and its therapeutic alternative(s), CMS will identify outcomes to evaluate for each indication of the selected drug. CMS will consider the identified outcomes, including patient-centered outcomes[67] and patient experience data, when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s). When reviewing such information, as noted above, CMS will not, per section 1194(e)(2), use evidence in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and will not, per section 1182(e) of the Act, use QALYs. Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients and patient-reported outcomes will also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug, including patient-centered outcomes when available. CMS may also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug. Relevant outcomes will be identified using the CMS-led literature review and information submitted by manufacturers and the public, including patients and caregivers, through the Negotiation Data Elements ICR described in section 50 of this revised guidance, as well as in the patient-focused listening sessions described in section 60.4.

In all cases, CMS will consider applicable evidence and other input collectively, within the context of the course of care for the condition(s) or disease(s) that the selected drug is indicated to treat, and in accordance with section 50 of this revised guidance. As noted previously, this approach provides flexibility to consider multiple perspectives on the clinical benefit of the selected drug and its therapeutic alternative(s), including potential risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience.

[67] A patient-centered outcome is defined as: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves. (Source: ISPOR Plenary, Patrick (2013) via FDA's *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders*, June 2020.) See: https://www.fda.gov/media/139088/download.

CMS will also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations as required by section 1194(e)(2)(C) of the Act. In doing so, CMS will evaluate access, equity, and health outcomes for specific populations. To do so, CMS will seek to identify studies focused on the impact of the selected drug and its therapeutic alternative(s) on individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries. Specific populations may include underserved and underrepresented populations, as applicable. Further, CMS will consider whether the selected drug fills an unmet medical need, which CMS will define as treating a disease or condition in cases where no other treatment options exist or existing treatments do not adequately address the disease or condition. CMS will consider each selected drug and its therapeutic alternatives to determine whether the drug fills an unmet medical need at the indication level as of the time the section 1194(e)(2) data is submitted. CMS will consider the nonbinding recommendations in the FDA's "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics,"[68] as well as any updates that may be issued by FDA in the future, when determining if a selected drug addresses an unmet medical need.

CMS will determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression). CMS understands that a selected drug can be first in class,[69] however, other drugs may have become available since the selected drug's initial approval. In accordance with section 1194(e)(2)(A) of the Act, CMS will review the analyses detailed above for each indication for the selected drug and its therapeutic alternative(s) and determine, based on the relevant information and evidence, what the difference in clinical benefit is between the selected drug and the therapeutic alternative(s).

As previously noted, CMS will take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug and its therapeutic alternative(s) as well as the patient population(s) taking the selected drug. For each selected drug, the applicable starting point will first be adjusted (i.e., apply an upward or downward adjustment, or no adjustment) based on the totality of the relevant information and evidence submitted and gathered through CMS' analysis based on the clinical benefit the selected drug provides (and then subsequently it will be adjusted by the manufacturer-submitted data described in section 60.3.4). Because the extent of clinical benefit may vary across different indications, CMS may adjust the starting point based on the clinical benefit for an individual indication in cases where the clinical benefit of the selected drug is notably different than the therapeutic alternative(s) for that specific indication.

60.3.3.2 Analysis for Selected Drugs Without Therapeutic Alternatives

Similar to a selected drug with at least one therapeutic alternative, the starting point for a selected drug without a therapeutic alternative will be adjusted based on the totality of relevant information and evidence as detailed above, such as outcomes and impact on specific

[68] FDA Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics, May 2014. See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics.

[69] First in class drugs are those that have a new mechanism of action, defined by the National Cancer Institute as "a term used to describe how a drug or other substance produces an effect in the body." See: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action.

populations, submitted through the Negotiation Data Elements ICR and gathered through CMS' analysis of the clinical benefit the selected drug provides.

CMS will consider whether the selected drug fills an unmet medical need separately for each indication. A selected drug will be considered to meet an unmet medical need for an indication included in the analysis when it is used to treat a disease or condition where no other treatment options exist or existing treatments do not adequately address the disease or condition. As noted previously, CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics," as well as any updates that may be issued by FDA in the future, when considering if a drug addresses an unmet medical need for the purpose of the Negotiation Program. A selected drug may be considered a therapeutic advance when a substantial improvement in outcomes is observed for an indication.

60.3.3.3 Preliminary Price

After the starting point has been adjusted, as appropriate, based on section 1194(e)(2) data submitted by manufacturers and the public through the Negotiation Data Elements ICR and gathered through CMS-led analyses and literature review, the resulting price is referred to as "the preliminary price." As described in section 60.3.4 of this revised guidance, the preliminary price will be adjusted, as appropriate, based on data submitted by the Primary Manufacturer in accordance with section 1194(e)(1) of the Act.

60.3.4 Adjusting the Preliminary Price Based on Consideration of Manufacturer-Specific Data

Under section 1194(e)(1) of the Act, CMS must also consider data reported by the Primary Manufacturer, as described in section 50.1 of this revised guidance. The adjustment to the preliminary price applied on the basis of these data, if any, may be upward or downward, as needed to account for these manufacturer-specific data elements. These data elements are: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug; and (5) market data and revenue and sales volume data for the drug in the United States.

CMS will consider the five elements outlined in section 1194(e)(1) of the Act in totality and apply an upward adjustment, downward adjustment, or no adjustment to the preliminary price. To do this, CMS may consider each factor in isolation or in combination with other factors. CMS provides illustrative examples for the manufacturer-specific data elements below. However, the overall adjustment, inclusive of all five elements taken together, may differ from the example adjustment for any single element viewed in isolation.

In considering element (1) above on R&D costs, CMS will consider the extent to which the Primary Manufacturer has recouped its R&D costs. CMS will compare the R&D costs with the global and U.S. total lifetime net revenue for the selected drug reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its R&D costs. For example, if a Primary Manufacturer has not recouped its R&D costs, CMS may

consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its R&D costs, CMS may consider adjusting the preliminary price downward or apply no adjustment. CMS may use the R&D costs reported by the Primary Manufacturer and the calculated recouped costs, including the assumptions and calculations in the accompanying narrative text, and/or other factors as described in the Negotiation Data Elements ICR and in Appendix C of this revised guidance to adjust the preliminary price.

In considering element (2) on current unit costs of production and distribution, CMS will consider the relationship between the preliminary price and the unit costs of production and distribution. For example, CMS may consider adjusting the preliminary price downward if the unit costs of production and distribution are lower than the preliminary price, or upward if the unit costs of production and distribution are greater than the preliminary price. Again, CMS may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug to determine if an adjustment is appropriate.

In considering element (3) on prior Federal financial support, CMS will consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug. For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

In considering element (4) on patent applications, exclusivities, and applications and approvals for the selected drug, CMS will review the patents and exclusivities reported as it develops its initial offer. CMS believes that this information will support CMS' consideration of the 1194(e)(1) and 1194(e)(2) factors described in section 50 of this revised guidance. For instance, patents and exclusivities may inform CMS' understanding of therapeutic alternatives and other available therapy for the purposes of adjusting for clinical benefit, including consideration of whether the selected drug represents a therapeutic advance or meets an unmet medical need. More specifically, in light of exclusivities, there may be no other available therapy aside from the selected drug that adequately addresses treatment or diagnosis of a disease or condition, and consideration of such information would be relevant to CMS' consideration of the extent to which the selected drug addresses an unmet medical need for that disease or condition.

Finally, in considering element (5) on market data and revenue and sales volume data for the U.S., CMS will consider how the data compare to the CMS preliminary price. For example, if the average commercial net price is lower than the preliminary price, CMS may consider adjusting the preliminary price downward. If the average commercial net price is greater than the preliminary price, CMS may consider adjusting the preliminary price upward.

Appendix C of this revised guidance includes a list of definitions that CMS adopts for the purposes of describing the data to be collected with respect to the data elements listed in section 1194(e)(1) of the Act.

After any adjustments to the preliminary price are made under this section 60.3.4 of this revised guidance, the result is the initial offer.

60.4 Negotiation Process

In accordance with sections 1191(b)(4)(A) and 1191(d)(2)(A) of the Act, and as described in section 40.1 of this revised guidance, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into an Agreement, or, for initial price applicability year 2026, October 1, 2023. CMS will implement the negotiation process consistent with the requirements of the statute, with the aim of achieving "the lowest maximum fair price for each selected drug" consistent with section 1194(b)(1) of the Act.

After the submission of the section 1194(e) data by manufacturers and other interested parties by October 2, 2023, CMS will host meetings with Primary Manufacturers of selected drugs that have submitted section 1194(e) data and other interested parties. CMS will invite the Primary Manufacturer for each selected drug to one meeting in Fall 2023 after the data submission deadline. The purpose of this meeting will be for the Primary Manufacturer to provide additional context on its data submission and share new section 1194(e)(2) data, if applicable, as CMS begins reviewing the data and developing an initial offer. Primary Manufacturers may bring materials to facilitate discussion and CMS may request any materials presented afterwards. Primary Manufacturers are limited to sharing 50 pages (or a combination of pages, slides, and/or charts and graphs totaling 50 pages) of material, in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting, anticipating that these materials may contain cross-references to other material, particularly other material already submitted to CMS. CMS will also host patient-focused listening sessions with interested parties. These meetings are intended to bring together patients, beneficiaries, caregivers, and consumer and patient organizations as well as other interested parties to share patient-focused feedback with CMS on therapeutic alternatives and other information as CMS reviews section 1194(e)(2) data submissions and develops an initial offer for each selected drug. More information about these listening sessions will be forthcoming.

CMS acknowledges that Primary Manufacturers may benefit from having access to the section 1194(e)(2) data submitted by other interested parties during the negotiation period. In addition to offering the meetings above, CMS will aim to share redacted section 1194(e)(2) data with the Primary Manufacturer of a selected drug during the negotiation process when feasible. The data will be redacted as per the confidentiality standards described in section 40.2 of this revised guidance and will not include proprietary information, PHI / PII, or information that is protected from disclosure under other applicable law.

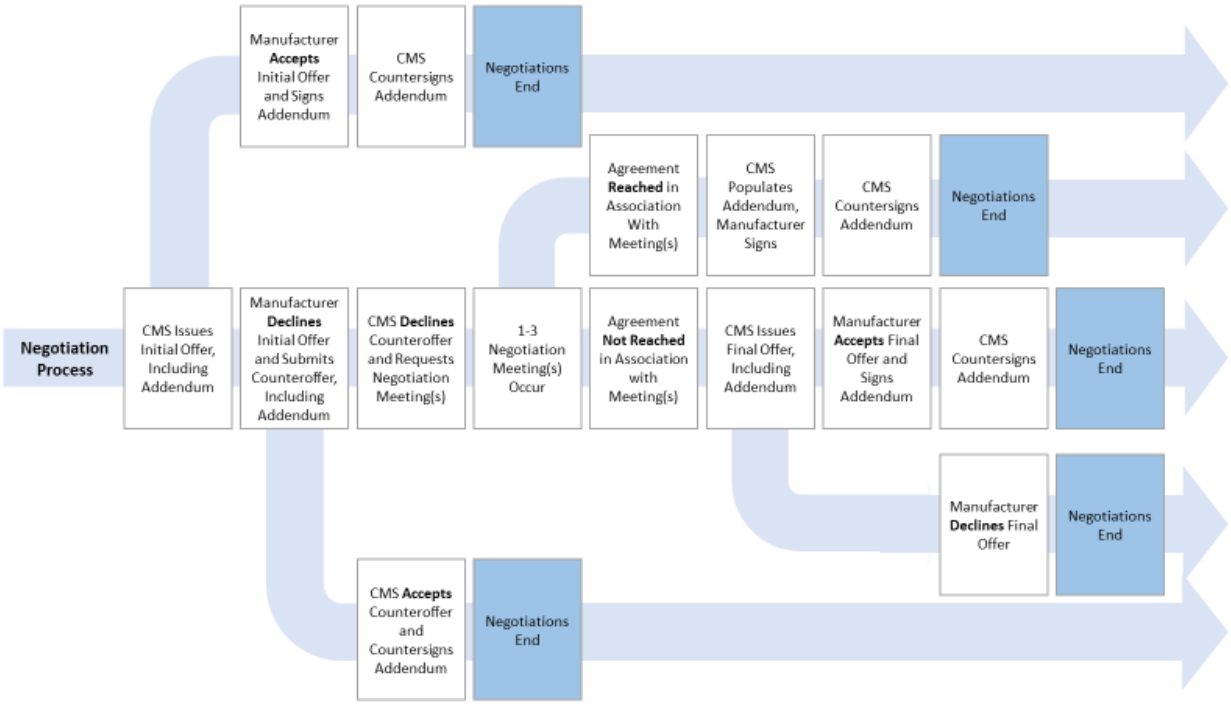
In accordance with sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug for initial price applicability year 2026 no later than February 1, 2024. This written initial offer will be accompanied by an Addendum to the Agreement populated with the proposal for the MFP, in order for CMS and the Primary Manufacturer to effectuate agreement upon the MFP if such agreement is reached at this stage.

After the written initial offer from CMS is sent to the Primary Manufacturer, the negotiation process may include the following steps, depending on when and whether agreement on the MFP is reached and an offer is accepted:

(1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer, including an Addendum populated with the counteroffer MFP as described in section 60.4.2 of this revised guidance, from the Primary Manufacturer (if CMS' written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer from CMS;
(2) in accordance with section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written manufacturer counteroffer, which CMS will provide within 30 days;
(3) if the Primary Manufacturer's written counteroffer is not accepted by CMS, up to three possible in-person or virtual negotiation meetings between the Primary Manufacturer and CMS; and
(4) a final written offer, including an Addendum containing the final offer MFP as described in section 60.4.4 of this revised guidance, made by CMS to the Primary Manufacturer, if no agreement is reached before the end of the negotiation meetings.

Every offer and counteroffer will include an Addendum populated with the offered/counteroffered MFP. If an agreement is reached at any point during the negotiation process by the Primary Manufacturer accepting CMS' written initial offer or final offer (as described in section 60.4.4 of this revised guidance), CMS accepting the Primary Manufacturer's counteroffer, or an agreement being reached in association with the negotiation meetings, the Addendum to the Agreement, as described in section 40.3 of this revised guidance, will be executed by both parties and will constitute agreement on the MFP. Section 60.4.4 of this revised guidance describes how and when the Addendum will be created and signed. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2026 and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable. The diagram below provides a non-exhaustive list of possible paths the negotiation process could take after CMS' initial offer, for a process taking place within the statutorily specified timelines.

Figure 3. Possible Negotiation Paths



During the entire negotiation process, CMS cannot offer or agree to any manufacturer counteroffer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and as described in section 60.2 of this revised guidance.

If the Primary Manufacturer is delayed in meeting one or more deadlines related to establishing the Agreement, submitting required data, and/or submitting the counteroffer, CMS will continue to engage in the negotiation process and will take the time to complete the established process as described in this section. During the period of time from when the Primary Manufacturer fails to meet a deadline until the date the Primary Manufacturer comes into compliance with the negotiation process, CMS will consider the Primary Manufacturer in violation of the Agreement and the Primary Manufacturer may be subject to civil monetary penalties as outlined in section 1197(c) of the Act. Section 90.3 and section 100 of this revised guidance further address possible actions to address noncompliance.

60.4.1 Provision of an Initial Offer and Justification

In accordance with section 1194(b)(2)(B) of the Act, the written initial offer from CMS, provided no later than February 1, 2024, must include a concise justification for the offer based on the data described in section 50 of this revised guidance. The justification will include a qualitative description of the factors from section 1194(e) (further described in sections 50 and 60.3 of this revised guidance) and a description of the methodology that CMS used to determine the initial offer. The information contained in the concise justification will provide the Primary Manufacturer with information on the range of evidence and other information considered pursuant to section 1194(e) that CMS found compelling during the development of the initial offer, thereby providing the Primary Manufacturer the necessary information to build a counteroffer if the Primary Manufacturer decides to reject the initial offer. The initial offer and

justification will not include information that CMS determines to be third-party proprietary pricing information, information that could lead to the calculation of a third party's proprietary information, PHI / PII, other information that is protected from disclosure under other applicable law, or the starting point.

No offer can exceed the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section 60.2 of this revised guidance. As feasible, CMS will provide information on the calculation of the statutorily-determined ceiling and the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer within 60 days of the Primary Manufacturer's submission of data that complies with the requirements described in section 50.1 of this revised guidance. As described in section 40.2.3 of this revised guidance, CMS may reach out to the Primary Manufacturer for clarity on its data submission if CMS determines the information is not complete or accurate. In situations when additional outreach to the Primary Manufacturer is required to clarify the submitted data, CMS will aim to provide information on the calculation of the statutorily-determined ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer as close to 60 days from the initial data submission as feasible. As described in section 40.5 of this revised guidance, a Primary Manufacturer will have 30 days to submit a suggestion of error regarding the calculation of the ceiling and computation of how CMS will apply a single MFP across dosage forms and strengths for CMS' consideration.

60.4.2 Required Components of a Counteroffer

In accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer will have no more than 30 days from receipt of the written initial offer from CMS to respond in writing by either accepting the initial offer for the selected drug or making a written counteroffer and providing a justification for such counteroffer based on the data described in section 50 of this revised guidance. Any counteroffer should also respond to the justification provided in CMS' written initial offer. The Primary Manufacturer's response should focus on the elements described in section 1194(e) and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the data in section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS. Primary Manufacturers may also include in their counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) that supports the counteroffer MFP.

The Primary Manufacturer should provide a suggested MFP for the selected drug in its written counteroffer. As described in section 60.1 of this revised guidance, the counteroffer MFP should be made consistent with the manner that CMS' written initial offer was made; that is, a single price for the cost of the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. In accordance with section 1194(b)(2)(F) of the Act, CMS cannot accept a written counteroffer from a manufacturer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section 60.2 of this revised guidance.

On April 18, 2023, CMS published the Drug Price Negotiation Process ICR for 60-day comment to capture information related to the counteroffer that Primary Manufacturers may submit after receiving CMS' initial offer.[70] The Drug Price Negotiation Process ICR includes instructions and a form for Primary Manufacturers to submit written counteroffers in the case where CMS' written initial offer of an MFP for a selected drug is not accepted. The comment period for the Drug Price Negotiation Process ICR closed on June 20, 2023. There will be an additional opportunity to submit comments for 30 days after revisions and re-publication in the Federal Register.

In order for a written counteroffer to be considered complete, a Primary Manufacturer must complete an Addendum in the CMS HPMS in addition to responding to the Drug Price Negotiation Process ICR, as described in section 40.3 of this revised guidance. A completed Addendum would include, but is not limited to, the MFP the Primary Manufacturer is counteroffering and a signature by an authorized representative.

60.4.3 Negotiation Process After Manufacturer Counteroffer

In accordance with section 1194(b)(2)(D) of the Act, CMS will respond in writing to a written counteroffer made by the Primary Manufacturer. Although the statute does not specify a timeframe for CMS' response to the counteroffer, negotiations for initial price applicability year 2026 must end prior to August 1, 2024, i.e., an agreement on MFP for the selected drug must be reached no later than July 31, 2024, to avoid potential excise tax liability under 26 U.S.C. § 5000D(b)(2).

In the case CMS' written initial offer is not accepted, and the Primary Manufacturer submits a written counteroffer, CMS will consider the counteroffer and either accept or reject it in writing within 30 days of receipt of the counteroffer. When considering a counteroffer, CMS will evaluate whether accepting the counteroffer is consistent with the statutory directive to aim to arrive at an agreement that achieves the lowest possible MFP for the selected drug. If CMS' written response to the counteroffer rejects the Primary Manufacturer's written counteroffer, CMS will extend an invitation to the Primary Manufacturer for a negotiation meeting. CMS will offer to hold a minimum of one meeting between CMS and the Primary Manufacturer to discuss CMS' written initial offer, the Primary Manufacturer's written counteroffer, and data considered. After this initial meeting, CMS will give each party (CMS and the Primary Manufacturer) the opportunity to request one additional meeting, resulting in a maximum of three meetings between CMS and the Primary Manufacturer.

The scope for these negotiation meetings will focus on the section 1194(e) data, including the therapeutic alternative(s) for the selected drug, and how they should inform the MFP. During these negotiation meetings, discussion of disputes and program policies regarding the negotiation process will be considered out of scope. CMS and the Primary Manufacturer will each be permitted to bring up to six meeting attendees, and both parties must share its participant lists ahead of each meeting. CMS arrived at this meeting attendee number after considering the roles from each party that would be critical to the conversation while ensuring that the meeting is sized appropriately to encourage active discussion. Additionally, a maximum of six attendees per side

[70] Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). See: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.

is in line with requirements for similar meetings between government entities and manufacturers. Each meeting will last no more than two hours and may be conducted in-person at CMS or HHS headquarters. CMS believes two hours per negotiation meeting (of which there can be up to three meetings) is sufficient for a fruitful discussion and is appropriate considering time and scheduling constraints. If necessary, due to distance or scheduling challenges, meetings may be held virtually, or may be a "hybrid" arrangement where a portion of attendees are in-person and a portion of attendees are virtual. CMS' notes from negotiation meetings will be retained as part of the meeting record in compliance with applicable federal law including the Federal Managers Financial Integrity Act and the Federal Records Act and will be subject to the confidentiality policy described in section 40.2.1 of this revised guidance. Attendees on behalf of the Primary Manufacturer may take and keep notes of the meetings. Audio and/or video recording of negotiation meetings will not be permitted.

Correspondence regarding negotiation meetings will be conducted over email using the IRARebateandNegotiation@cms.hhs.gov mailbox. CMS will share a meeting agenda with the Primary Manufacturer via email approximately two weeks before the meeting. The Primary Manufacturer may request additions or edits to the agenda as long as they are in scope, as discussed in the paragraph above. Such requests must be submitted via email at least one week ahead of the meeting. CMS will circulate a final agenda two business days prior to the negotiation meeting. If a Primary Manufacturer would like to share materials at a negotiation meeting, such materials should be limited to 20 pages (or a combination of pages, slides, and/or charts and graphs totaling 20 pages), in order to focus the discussion on issues that can reasonably be discussed within the scope of the meeting, anticipating that these materials may contain cross-references to other material, particularly other material already submitted to CMS. Such materials must be submitted via email at least one week ahead of the meeting. Substantive discussion via email will not be permitted, in order for all attendees to benefit from such discussions as part of the negotiation meetings.

The meetings for initial price applicability year 2026 will occur between the time the Primary Manufacturer's written counteroffer is not accepted by CMS, which at the latest will be 30 days after the counteroffer is received, if applicable, and June 28, 2024. There would be about three months' time between CMS' rejection of the Primary Manufacturer's written counteroffer (approximately April 1, 2024) and the deadline for negotiation meetings to conclude (June 28, 2024). CMS requires that all negotiation meetings end no later than June 28, 2024, the last business day that is fifteen days prior to July 15, 2024, to allow CMS sufficient time to prepare a final offer (if an MFP was not reached in association with the negotiation meetings), send that final offer to the Primary Manufacturer by July 15, and to allow the Primary Manufacturer time to consider the final offer and accept or reject the final offer by July 31, 2024, as all negotiations must be concluded prior to August 1, 2024. These dates assume that a Primary Manufacturer is timely in entering into an Agreement, submitting information, and meeting deadlines related to the Negotiation Program.

CMS believes that the negotiation meeting process described above allows for a more efficient and effective approach than preparing and exchanging additional written offers and counteroffers. Negotiation meetings will also allow both parties to discuss any new information consistent with the data described in section 1194(e)(2) of the Act that may have become

available about the selected drug or its therapeutic alternative(s), and that may affect the determination of the MFP. Negotiation meetings will be attended solely by representatives of the Primary Manufacturer and of CMS. A written record will be developed and retained by CMS in compliance with applicable federal laws. The Primary Manufacturer can also develop and retain its own written record. As described in section 40.2.2 of this revised guidance, CMS will not publicly discuss ongoing negotiations with a Primary Manufacturer, including details of the negotiation meetings. Primary Manufacturers may publicly disclose information regarding ongoing negotiations with CMS at its discretion. If a Primary Manufacturer discloses information that is made public regarding any aspects of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer.

As described in section 60.6.1 of this revised guidance, in this public explanation, CMS will make public a narrative explanation of the negotiation process and the agreed-upon MFP and share redacted information regarding the section 1194(e) data received, the exchange of offers and counteroffers, and the negotiation meetings while abiding by the confidentiality policy described in section 40.2 of this revised guidance.

When developing this negotiation process, CMS considered using solely a written offer and counteroffer approach. That is, CMS considered providing one written offer and allowing a Primary Manufacturer to make a single written counteroffer, as described in the statute. CMS also contemplated allowing each party to make up to two written offers or counteroffers (i.e., CMS makes an initial offer, Primary Manufacturer possibly makes a counteroffer, CMS possibly makes a second offer, Primary Manufacturer possibly makes a second counteroffer). However, CMS believes that an offer/counteroffer process that includes in-person or virtual meetings (or a hybrid approach) will most effectively facilitate the negotiation process to arrive at an MFP and is more consistent with current industry practices for drug price negotiation.

60.4.4 Determination that Negotiations Have Finished

In accordance with sections 1194(b)(2)(E) and 1191(d)(2)(B) of the Act, all negotiations between CMS and the manufacturer of the selected drug must end prior to August 1, 2024, for initial price applicability year 2026 to avoid potential excise tax liability.

In the event that negotiation meetings occurred and an MFP was not agreed to in association with the negotiation meetings, CMS will send the Primary Manufacturer a “Notification of Final Maximum Fair Price Offer” and an Addendum with the final offer MFP by July 15, 2024. This will serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. This final offer will only be sent if, by July 15, 2024, neither CMS nor the Primary Manufacturer has accepted the latest offer or counteroffer made in writing or agreed upon an MFP in association with the negotiation meetings. If a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by July 31, 2024. The following table details CMS’ timing for the negotiation process for initial price applicability year 2026:

Date[71]	Milestone
February 1, 2024	Statutory deadline for CMS to send written initial offer to the Primary Manufacturer
30 days after receipt of written initial offer from CMS (March 2nd if the offer is made by CMS on February 1, 2024)	Statutory deadline for the Primary Manufacturer to accept the initial offer or submit a written counteroffer to CMS
30 days after receipt of the manufacturer counteroffer (April 1st if the manufacturer counteroffer is made on March 2, 2024)	Date by which CMS will provide a written response accepting or rejecting the manufacturer counteroffer
Date that the Primary Manufacturer's written counteroffer is not accepted by CMS through June 28, 2024 (the last business day that is fifteen days prior to July 15, 2024)	Negotiation meetings (in-person, virtual, or hybrid, maximum of three possible meetings), if necessary
July 15, 2024	Date by which CMS will issue a "Notification of Final Maximum Fair Price Offer" to the Primary Manufacturer, if the written initial offer or Primary Manufacturer written counteroffer was not accepted and an MFP was not agreed upon in association with the negotiation meetings
July 31, 2024	Date by which the Primary Manufacturer must respond to (i.e., accept or reject) CMS' "Notification of Final Maximum Fair Price Offer," if applicable
July 31, 2024	Statutory deadline for all negotiations to end; CMS will notify the Primary Manufacturer of any failure to meet the deadline and the possible consequences thereof if agreement upon the MFP is not reached by July 31, 2024
August 1, 2024	Statutory end of negotiation period

To formalize agreement on an MFP, CMS and the Primary Manufacturer both sign an Addendum to the Agreement (described in sections 40.3 and 60.4 of this revised guidance) that sets forth the agreed-upon MFP. When CMS prepares a written offer, CMS also completes the Addendum with the offered MFP and sends the Addendum along with the written offer to the Primary Manufacturer via CMS HPMS. If the Primary Manufacturer accepts the written offer, they will sign the Addendum after which CMS will countersign the Addendum. Similarly, a

[71] These dates are contingent on CMS and the Primary Manufacturer meeting the deadlines described in this revised guidance and in statute. If the Primary Manufacturer is delayed in meeting one or more deadlines, CMS will continue to engage in the negotiation process and will take the time to complete the established process as described in this section. If a statutory deadline is missed, the Primary Manufacturer may be subject to a civil monetary penalty or excise tax.

Primary Manufacturer's written counteroffer is not considered complete unless the Primary Manufacturer submits a complete response to the Drug Price Negotiation Process ICR in CMS HPMS, submits an Addendum for the MFP consistent with the counteroffer amount in CMS HPMS, and signs that Addendum. If CMS accepts the written counteroffer, it will countersign the Addendum.[72]

If CMS and the Primary Manufacturer do not agree to an MFP by the statutory end of the negotiation period, the Primary Manufacturer will enter a period during which an excise tax potentially may be assessed. As described in 26 U.S.C. § 5000D(b)(2) and § 5000D(c), the Primary Manufacturer can end the period during which the excise tax may apply by agreeing to an MFP, as described in section 60.8 of this revised guidance, or can meet the statutory criteria for the suspension of tax or may terminate its Agreement in the manner described in section 40.6 of this revised guidance, which includes sending a notice terminating all of their applicable agreements under the Medicare and Medicaid programs and establishing that none of the Primary Manufacturer's drugs are covered by an agreement under section 1860D-14A or section 1860D-14C of the Act.

60.5 Application of the MFP Across Dosage Forms and Strengths

An MFP that is agreed upon as described in section 60.4 of this revised guidance establishes one price for the selected drug. In accordance with section 1196(a)(2) of the Act, CMS has the administrative duty to establish procedures to compute and apply the MFP across different dosage forms and strengths of the selected drug and not based on the specific formulation or package size or package type of such drug.

As described in section 60.1 of this revised guidance, the MFP will reflect a single price for the selected drug per 30-day equivalent supply. To ensure that the MFP is made available to MFP-eligible individuals at the point of sale (and to pharmacies, mail order services, or other dispensers, with respect to such MFP-eligible individuals), however, CMS will publish the MFP at the per-unit (e.g., tablet) level for each NDC-9 and NDC-11 associated with the selected drug.

The following methodology will be used to apply the single MFP across NDC-9s for a 30-day equivalent supply and to calculate an MFP per unit for each NDC-9 of the selected drug. CMS will use a methodology that scales the MFP per unit based on price differentials across different dosage forms and strengths. For initial price applicability year 2026, CMS will use the WAC of the selected drug in this calculation. CMS will first calculate an annual WAC per unit cost for each NDC-11 included on the list of NDC-11s of the selected drug in the CMS HPMS, inclusive of any NDC-11s added by the Primary Manufacturer (see section 40.2 of this revised guidance), from the manufacturer-submitted quarterly WAC per unit and unit volume data, to account for potential variation in unit volume across quarters. The annual WAC per unit for each NDC-11 will then be converted into an amount for a 30-day equivalent supply (using the methodology described in 42 C.F.R. § 423.104(d)(2)(iv)(A)(2)), so that the WAC will be comparable to the negotiated single MFP. CMS will then aggregate the WAC per 30-day equivalent supply for each NDC-11 into a WAC per 30-day supply for each NDC-9 of the selected drug. The WAC per 30-day equivalent supply for each NDC-9 will then be used to calculate a WAC price ratio

[72] In the event that this functionality is delayed in CMS HPMS, CMS will specify an alternative approach for sharing the Addendum in writing.

for each NDC-9 of the selected drug. The ratio derived from the WAC per 30-day equivalent supply for each NDC-9 will then be multiplied by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each NDC-9 of the selected drug. Lastly, to determine the per unit MFP for an NDC-9, CMS will convert from an MFP for a 30-day equivalent supply to an MFP per unit based on the average number of units in a 30-day equivalent supply.

The following steps provide additional detail regarding the approach CMS will use:

1. For each NDC-11 and calendar quarter, CMS will divide the WAC quarterly units by the total WAC annual units (from- manufacturer submitted data) and multiply this quotient by the quarterly WAC per unit.
    - Note: CMS will use the WAC unit cost for the period beginning January 1, 2022 and ending December 31, 2022 for purposes of this calculation to align with the time period of data used to calculate the ceiling for the MFP.
2. For each NDC-11, CMS will then sum the amounts calculated in step 1 to calculate the annual WAC per unit.
3. For each NDC-11, CMS will divide the quantity dispensed by the total 30-day equivalent supply, both calculated from 2022 PDE data, to calculate the average number of units per 30-day equivalent supply.
4. For each NDC-11, CMS will multiply the WAC per unit calculated in step 2 by the average number of units per 30-day equivalent supply calculated in step 3 to calculate the WAC per 30-day equivalent day supply for that NDC-11.
5. For each NDC-11, CMS will divide the total 30-day equivalent supply for that NDC-11 by the total 30-day equivalent supply across all applicable NDC-11s within an NDC-9 and then multiply this quotient by the amount calculated in step 4.
6. For each NDC-9, CMS will then sum amounts calculated in step 5 across all NDC-11s to calculate the WAC per 30-day equivalent supply for that NDC-9.
7. For each NDC-9, CMS will divide the total 30-day equivalent supply for that NDC-9 by the total 30-day equivalent supply across all NDC-9s and then multiply this quotient by the amount calculated in step 6.
8. CMS will then sum amounts calculated in step 7 across all NDC-9s of the selected drug to calculate the WAC per 30-day equivalent supply for the selected drug.
9. For each NDC-9, CMS will then divide the WAC per 30-day equivalent day supply for that NDC-9 calculated in step 6 by the WAC per 30-day equivalent supply for the selected drug calculated in step 8 to calculate the WAC per 30-day equivalent supply ratio for that NDC-9.
10. For each NDC-9, CMS will multiply the single MFP for the selected drug by the relative WAC per 30-day equivalent supply ratio for that NDC-9 calculated in step 9 to calculate the MFP per 30-day equivalent supply for that NDC-9.
11. For each NDC-9, CMS will divide the MFP per 30-day equivalent supply for that NDC-9 calculated in step 10 by the quotient of the total number of units dispensed divided by the total 30-day equivalent supply to calculate the MFP per unit (e.g., tablet).

CMS will include the MFP per unit price for each NDC-9 of the selected drug, calculated in step 11 of this section 60.5 of this revised guidance, along with corresponding NDC-11 package prices (determined by multiplying the NDC-9 unit price by the number of units per NDC-11 package), in the publication of MFPs as described in section 60.6 of this revised guidance. CMS

recognizes there may be other ways to apply the MFP to dosage forms and strengths and will monitor whether this policy serves the intent of the Negotiation Program. As noted throughout this revised guidance, the policies described for the Negotiation Program are for initial price applicability year 2026, and CMS may consider additional policies for future years of the Negotiation Program.

60.5.1 Application of the MFP to New NDAs / BLAs or NDCs

Based on the definition of a qualifying single source drug described in section 30.1 of this revised guidance, if the Primary Manufacturer for a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety / active ingredient after the drug has been selected, CMS requires that the MFP apply to drug or biological products marketed pursuant to the new NDA or BLA. Similarly, after the drug is selected, if the Primary Manufacturer for such drug receives approval or licensure for a new drug or biological product or NDC that is marketed pursuant to a supplement to an existing NDA or BLA, CMS requires that the MFP apply to such new drug or biological product. Additionally, an NDC that has been marketed pursuant to an applicable NDA or BLA prior to drug selection may lack sufficient PDE or WAC data in 2022 to apply the MFP across that dosage form and strength as described above. To apply the MFP to a new NDC that is marketed for the first time after the MFP is negotiated for a selected drug (including before or after the start of the initial price applicability year) or to an NDC that is marketed prior to MFP negotiation but which lacks either sufficient PDE unit data for calendar year 2022 or sufficient WAC data for calendar year 2022 for CMS to apply the MFP to that dosage form and strength as described above, CMS will determine whether there is an existing, comparable NDC to which the MFP for the selected drug has been applied. If a comparable NDC exists, CMS will impute the quotient of total quantity dispensed to 30-day equivalent supply based on the FDA-approved label associated with the new NDC and will use the same WAC ratio that was calculated for the existing NDC to apply the MFP to the new NDC.

If a comparable NDC does not exist, CMS will impute the quotient of total quantity dispensed to 30-day equivalent supply based on the FDA-approved label associated with the new NDC but will use a WAC ratio of 1.0 to apply the MFP to the new NDC.[73]

60.6 Publication of the MFP

In accordance with section 1191(d)(6) and section 1195(a)(1) of the Act, CMS will publish by September 1, 2024, the MFP for each drug selected for initial price applicability year 2026 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Related to this requirement, CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file, and the explanation for the MFP (published at a later date – see section 60.6.1 of this revised guidance). The MFP file will contain the single MFP for a 30-day equivalent supply of the selected drug, the NDC-9 per unit price, and NDC-11 per package price and will be updated annually to show the inflation-adjusted MFP for the selected drug. CMS will also publish on the CMS website when a drug is no longer a selected drug and

[73] While this guidance is focused on initial price applicability year 2026, CMS notes that in future years, renegotiation of the MFP might be appropriate in the event of certain new NDCs that represent material changes to the selected drug, such as where the new NDC is sought due to changes in the selected drug that result in the addition of a new indication. CMS will provide additional information in the future on renegotiation, which will be implemented for initial price applicability year 2028 and subsequent years, in accordance with the statute.

the reason for that change, and when an MFP between a Primary Manufacturer and CMS is not agreed upon.

60.6.1 Explanation for the MFP

Section 1195(a)(2) of the Act requires CMS to publish an explanation for the MFP no later than March 1 of the year prior to the initial price applicability year, which will be March 1, 2025 for initial price applicability year 2026. CMS will strive to publish these explanations earlier than March 1, 2025, if feasible. The explanation will focus on the section 1194(e) data that had the greatest impact in determining the MFP and include a discussion of the other section 1194(e) data, as applicable. It will also note any data or circumstances that may be unique to the selected drug. Alongside the narrative explanation, CMS will release redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. CMS will develop and publish the public explanation of the MFP in accordance with the confidentiality policy described in section 40.2 of this revised guidance.

If an agreement for an MFP is not reached for a selected drug, neither an MFP nor a public explanation of the MFP will be published. Instead, CMS will indicate on the CMS website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug. In circumstances where an MFP is finalized after the statutory deadline for the conclusion of negotiations, the MFP and the public explanation of the MFP will be posted in accordance with section 60.8 of this revised guidance.

60.7 Exclusion from the Negotiation Process Based on Generic or Biosimilar Availability

In accordance with section 1192(c)(2) of the Act and subject to the timeline and situations discussed in section 70, a selected drug will no longer be subject to the negotiation process, with respect to its initial price applicability year, if CMS determines that at least one generic drug or biosimilar biological product satisfies the following criteria: (1) it is approved under section 505(j) of the FD&C Act with at least one dosage form and strength of the selected drug as the listed drug or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product, and (2) it is marketed pursuant to such approval or licensure. The approach CMS will take to make this determination is described in section 70 of this revised guidance.

When the drug is no longer subject to the negotiation process based on the criteria in section 1192(c)(2) of the Act, the selected drug will continue to be considered a selected drug with respect to such initial price applicability year with respect to the number of negotiation-eligible drugs on the list published under section 1192(a) of the Act (see section 70 of this revised guidance for additional details).

60.8 Establishment of MFPs After the Negotiation Deadline

Sections 1194(b)(2) and 1191(d)(5)(C) of the Act contemplate that agreement upon an MFP must be reached for initial price applicability year 2026 by August 1, 2024 in order to avoid potential imposition of an excise tax. If negotiations have not ended by this date, the Primary Manufacturer may be subject to an excise tax. As a general matter, if the Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, CMS will continue to engage in the negotiation process described in section 60.4 of this revised guidance.

Certain actions or delays by the Primary Manufacturer may delay the process such that the MFP is established after the end of the negotiation period. If this occurs, in accordance with section 1194(b)(1) of the Act, CMS will follow timelines consistent with the negotiation process established in this revised guidance and take the time to complete the established process so described as appropriate for the selected drug. Likewise, certain actions by the Primary Manufacturer may delay the negotiation process to such an extent that a selected drug has a change in status that is material to CMS' statutory obligations under the negotiation process. If this occurs, in accordance with section 1194(b)(1), when CMS initiates or resumes the negotiation process, CMS will apply the consistent methodology and process with respect to the selected drug based on its status at the time the negotiation process occurs, including beginning in 2028 which may have potential implications with respect to the renegotiation process. Guidance about the renegotiation process will be forthcoming for future years of the Negotiation Program.

If the manufacturer and CMS have completed each step of the negotiation process as detailed in section 60.4 of this revised guidance, including CMS' issuance of a "Notification of Final Maximum Fair Price Offer" and then, after the statutory end of the negotiation period, the Primary Manufacturer of a selected drug wishes to agree to an MFP, the Primary Manufacturer must notify CMS in writing that it would like to accept the last offer of an MFP from CMS, as reflected in the "Notification of Final Maximum Fair Price Offer." In accordance with section 1195(b)(2) of the Act, in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, CMS shall publish the MFP no later than 30 days after the date such MFP is so determined. In accordance with section 60.6 of this revised guidance, CMS will publish the MFP and the MFP explanation on the CMS website. CMS will follow timelines consistent with the established process for publishing the public explanation of the MFP and will not expedite its timeline due to late action from the Primary Manufacturer.

70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

In accordance with section 1192(c) of the Act, a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug, subject to the timeline and situations discussed below, if CMS determines (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure.

The approval (or licensure, as applicable) and marketing of an authorized generic drug (which includes authorized generic drugs and certain biological products as defined in section 1192(e)(2) of the Act) would not qualify as meeting the statutory requirement that a generic drug or a biosimilar biological product is being marketed. In accordance with section 1192(e)(2)(B)(i) of the Act, an authorized generic drug as defined in section 505(t)(3) of the FD&C Act is treated as the same qualifying single source drug as a qualifying single source drug that is the listed drug, for the purposes of the Negotiation Program. Likewise, section 1192(e)(2)(B)(ii) of the Act indicates that the same rule applies to a biological product that is approved under section 351(a)

of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under different labeling or packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark.

The determination whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list will be informed by CMS' review of PDE and AMP data for the generic drug or biosimilar biological product for which the selected drug is the listed drug or reference product on a monthly basis as described below. CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when the totality of the circumstances, including these data, reveals that the manufacturer of the generic drug or biosimilar biological product is engaging in bona fide marketing of that drug or product.

After the selected drug is removed from the selected drug list, CMS will monitor the manufacturers of such generic drugs or biosimilar biological products to ensure they continue to engage in bona fide marketing of the generic or biosimilar biological product based on the process described in section 90.4 of this revised guidance.

Starting in October 2023, and repeated each month thereafter, CMS will take the following approach in its review of data to inform its determination whether the statutory criteria in sections 1192(c)(1)(A) and 1192(c)(1)(B) of the Act for an approved generic drug or licensed biosimilar to be marketed pursuant to such approval or licensure are being met.

First, CMS will use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar biological product is approved or licensed for any strength(s) or dosage form(s) of a selected drug for initial price applicability year 2026.

Second, if CMS determines that a generic drug or biosimilar biological product has been approved or licensed, CMS will begin by reviewing the PDE and AMP data with dates of service during the most recent 12-month period available to determine if the manufacturer of the generic drug or biosimilar biological product has engaged in bona fide marketing of that drug or product. For example, when CMS performs this assessment in October of 2023, CMS will use PDE and AMP data with dates of service from October 2022 through September 2023. When CMS performs this assessment in November 2023, CMS will use PDE and AMP data for dates of service from November 2022 through October 2023.

The determination whether a generic drug or biosimilar is being bona fide marketed is a totality-of-the-circumstances inquiry that will not necessarily turn on any one source of data. Additional relevant factors may include whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug, as articulated further in section 90.4.

Per section 1192(c)(2) of the Act, if CMS makes a determination regarding generic drug or biosimilar biological product availability on or after the selected drug publication date, and

before the end of or during the negotiation period for an initial price applicability year, the selected drug will not be subject to the negotiation process for the negotiation period, and an MFP will not be established. Accordingly, for initial price applicability year 2026, if CMS makes this determination between September 1, 2023, and August 1, 2024, the drug will remain a selected drug through 2026, but no MFP will apply and the drug will not be replaced with another selected drug.

In accordance with section 1192(c)(1) of the Act, a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines the statutory criteria in section 1192(c) are met. Accordingly, if CMS makes this determination between August 2, 2024, and March 31, 2026, for a drug selected for initial price applicability year 2026, then the drug will cease to be a selected drug on January 1, 2027, and the MFP will apply for 2026. If CMS makes this determination between April 1, 2026, and March 31, 2027, then the selected drug will cease to be a selected drug on January 1, 2028, and the MFP will apply for 2026 and 2027. These results are summarized in the following table:

Date on which CMS determines that a generic drug or biosimilar biological product is approved and marketed	**Result with respect to selected drug for the Negotiation Program**
September 1, 2023 through August 1, 2024 (which includes the Negotiation Period for the initial price applicability year 2026)	Selected drug remains a selected drug for initial price applicability year 2026, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2027.
August 2, 2024 through March 31, 2026	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026; selected drug ceases to be a selected drug on January 1, 2027.
April 1, 2026 through March 31, 2027	Selected drug remains a selected drug and MFP applies for initial price applicability year 2026 and calendar year 2027; selected drug ceases to be a selected drug on January 1, 2028.

Without regard to whether the Primary Manufacturer decides to execute an Agreement as discussed in section 40.1 of this revised guidance, to terminate an Agreement as discussed in section 40.6, or to transfer ownership of the selected drug as discussed in section 40.7, a selected drug remains a selected drug until CMS determines otherwise under the criteria set forth in section 1192(c) of the Act.

In all cases, after CMS determines the statutory criteria in section 1192(c) for generic competition are met for a selected drug, CMS will publish such information on the CMS website.

80. MFP-Eligible Individuals

For initial price applicability year 2026, in accordance with section 1191(c)(2) of the Act, the term “maximum fair price eligible individual” means, with respect to a selected drug, the

following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including an Employer Group Waiver Plan), if Part D coverage is provided under such plan for such selected drug. The MFP is not required to be made available to a Medicare beneficiary who uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash.[74] For initial price applicability year 2026, CMS does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to MFP eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan.

90. Manufacturer Compliance and Oversight

In accordance with section 1196(b) of the Act, CMS will monitor compliance by a Primary Manufacturer with the terms of the Agreement and establish a mechanism through which violations of such terms shall be reported.

90.1 Monitoring of Manufacturer Compliance

CMS will closely monitor the Primary Manufacturer's compliance with the terms of the Agreement and other aspects of the Negotiation Program. Following the publication of selected drugs for each initial price applicability year, CMS will provide information about the negotiation process to the Primary Manufacturer of each selected drug (see section 40 of this revised guidance for additional details). CMS anticipates this information will include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information.

During the negotiation period, CMS will track and monitor progress during all steps of the process and engage in direct communications with each Primary Manufacturer. To facilitate successful Negotiation Program operations and support manufacturer compliance with Program requirements, CMS will issue reminder letters prior to manufacturer deadlines with warnings of potential applicability of excise taxes (see 26 U.S.C. § 5000D for additional information regarding the excise tax) or CMPs (see section 100 of this revised guidance), written requests for corrective action when applicable (see section 40.2.3 of this revised guidance), written notification that a Primary Manufacturer may be subject to enforcement action as applicable, and written confirmation that a Primary Manufacturer may no longer be subject to enforcement action as applicable.

Failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program may result in potential excise tax liability (see 26 U.S.C. § 5000D). As described in section 100 of this revised guidance, failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program could result in CMPs.

[74] CMS notes that employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage are not included because they are not Part D plans.

90.2 Monitoring of Access to the MFP

In accordance with section 1193(a)(3)(A) of the Act, under the Agreement with CMS with respect to a price applicability period, access to the MFP with respect to such a selected drug shall be provided by the Primary Manufacturer to MFP-eligible individuals at the pharmacy, mail order service, or other dispenser at the point of sale, and to the pharmacy, mail order service, or other dispenser with respect to such MFP-eligible individuals who are dispensed the selected drug.

Further, in accordance with section 1193(a)(5) of the Act, which requires that the manufacturer comply with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program, and section 40.4 of this revised guidance, CMS requires that the Primary Manufacturer establish safeguards to ensure the MFP is available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers on units of the selected drug for which there are Secondary Manufacturers. CMS reiterates that the requirement for the Primary Manufacturer to provide access to the MFP applies to all sales of the selected drug by a Secondary Manufacturer to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual, as discussed in section 80 of this revised guidance.

As described in section 40.4 of this revised guidance, CMS is considering the potential to engage with an MTF to facilitate the exchange of data between supply chain entities to support the verification of MFP eligibility of an individual who is dispensed a selected drug. Each component of the pharmaceutical supply chain may have a role in making the MFP available to MFP-eligible individuals, but it is ultimately the Primary Manufacturer's responsibility to ensure access to the MFP. There are various methods by which dispensing entities and MFP-eligible individuals can determine whether they are accessing the MFP for a selected drug.

For example, under section 1195(a) of the Act, the MFP for a selected drug will be published by CMS, giving the public and other interested parties an opportunity to know the MFP for each selected drug, as well as the explanation for each MFP (see section 60.6 of this revised guidance for additional details). Under section 1191(d)(6), the MFPs for selected drugs for initial price applicability year 2026 must be published by September 1, 2024. In addition, CMS anticipates that pharmaceutical database compendia will publish the MFPs for selected drugs such that they would become more knowable and accessible to pharmaceutical purchasers. CMS believes such transparency of the MFPs for selected drugs will help dispensing entities and MFP-eligible individuals to know the MFP for a selected drug and determine whether they are able to access the MFP.

In accordance with section 1196(a)(3)(A) of the Act, as well as section 1196(b), which requires that the Secretary establish a mechanism by which violations of the terms of the Agreement shall be reported, CMS will establish procedures for reporting suspected violations related to access to the MFP with respect to MFP-eligible individuals who are enrolled in Medicare Part D plans and the pharmacies, mail order services, and other dispensers that provide selected drugs to MFP-eligible individuals. As part of this process, CMS may establish a toll-free phone line and email box where an individual or a dispenser could communicate information to CMS regarding an incident in which the MFP was not provided to an MFP-eligible individual or the applicable

pharmacy, mail order service, or other dispenser. CMS anticipates the submissions would likely include the name of the individual reporting the incident, the nature of the incident, the date the incident occurred, the name of the drug, the manufacturer of the drug, and contact information for follow-up.

Upon receipt of a report of a suspected violation, CMS will review the submissions, investigate reports of potential noncompliance, and if appropriate, impose CMPs on the Primary Manufacturer if CMS determines the Primary Manufacturer failed to provide an MFP-eligible individual or an eligible dispenser access to the MFP for the selected drug, including in cases where there are one or more Secondary Manufacturers of the selected drug. CMS would also expect manufacturers and other interested parties to report instances in which a dispenser was not passing through the MFP to an MFP-eligible individual, or a dispenser was extending the MFP to non-MFP-eligible individuals.

As described in section 40.4.1 of this revised guidance and consistent with section 1193(d) of the Act regarding the manufacturer's Agreement with CMS, a manufacturer with a Pharmaceutical Pricing Agreement (PPA) with the Secretary under the 340B program is not required to provide a 340B covered entity with access to the MFP of a selected drug with respect to an MFP-eligible individual who is eligible to be dispensed such selected drug at the covered entity if the 340B ceiling price is lower than the MFP for such selected drug.

CMS is also aware that it is conceptually possible for an entity that meets the statutory definition of a manufacturer, but that is not the Primary Manufacturer or a Secondary Manufacturer, to market one or more drug or biological products pursuant to one or more NDA(s) or BLA(s) included in the selected drug. For example, it is possible for an entity to purchase one or more drug or biological products included in the selected drug from a wholesaler, repackage or relabel such products, and then re-market them pursuant to one or more NDA(s) or BLA(s) included in the selected drug. CMS believes it would be appropriate for the MFP to be made available to all MFP-eligible individuals and to all pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals who are dispensed units of the selected drug. However, for initial price applicability year 2026, CMS is limiting the scope of Primary Manufacturer responsibility to provide access to the MFP for the selected drug to units of such drug sold by the Primary Manufacturer or a Secondary Manufacturer. CMS will monitor to determine if there are sales of selected drug to MFP-eligible individuals by manufacturers other than Primary Manufacturer and Secondary Manufacturers and consider whether other mechanisms are needed to promote access to MFP to Medicare-eligible individuals in these circumstances. CMS continues to seek feedback on how it might achieve this goal, interested parties can send feedback on this topic to IRARebateandNegotiation@cms.hhs.gov.

90.3 26 U.S.C. Section 5000D Excise Tax on Sale of Designated Drugs

The IRS will administer the excise tax. CMS understands that the Treasury Department will issue guidance relating to the excise tax in the coming weeks.

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

If CMS determines that either:

(1) a potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2026 because any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product, as applicable, for one or more generic drugs or biosimilar biological products that CMS determined are approved or licensed and marketed based on the process described in section 30.1 of this revised guidance, or

(2) a selected drug is no longer subject to the negotiation process and ceases to be a selected drug because (a) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (b) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure in accordance with section 1192(c) of the Act and under the process described in sections 60.7 and 70 of this revised guidance,

then CMS will monitor, after such an above determination is made, whether meaningful competition continues to exist in the market by ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing. Such monitoring by CMS may include, but is not limited to, whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug.

CMS is aware that marketing or other agreements between the Primary Manufacturer and generic drug or biosimilar manufacturers may limit the availability of the generic drug or biosimilar for purchase through the pharmaceutical supply chain, and CMS will attempt to identify when such agreements exist as a factor in determining whether bona fide marketing exists, although such agreements would not by themselves be dispositive of that determination. CMS notes that any agreements limiting the availability of a selected drug may be subject to scrutiny and potential enforcement under antitrust laws (including laws prohibiting unfair methods of competition) as well as laws prohibiting unfair or deceptive acts or practices in or affecting commerce.

In addition, CMS will analyze the share of generic drug or biosimilar biological product units identified in PDE data as a percentage of total units of Part D expenditures, as well as whether manufacturers are reporting units of the selected drug as part of their AMP reporting responsibilities under section 1927(b)(3)(A) of the Act, and the trend in reporting of such AMP units. CMS reserves the right to also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar.

100. Civil Monetary Penalties

In accordance with section 1197 of the Act, Primary Manufacturers of selected drugs that enter into an Agreement may be subject to CMPs for (1) failure to ensure access to a price that is less than or equal to the MFP for MFP-eligible individuals and pharmacies, mail order services, and

other dispensers who dispense the selected drug with respect to MFP-eligible individuals, (2) failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but has since undergone negotiation, as described in section 1192(f)(4) of the Act, (3) violation of certain terms of the Agreement, and (4) the provision of false information as described in section 1197(d) of the Act.

CMS' primary goal is to successfully administer all aspects of the Negotiation Program; CMS intends to exercise the authority to impose CMPs for instances of noncompliance that substantively obstruct negotiation processes and/or availability of the MFP Such instances may include, but are not limited to, failure to make the MFP available to MFP-eligible individuals; failure to provide timely, complete, and accurate information that is necessary to execute the negotiation process or other administrative or monitoring functions of the Negotiation Program; repeated violations of the Agreement or other Negotiation Program requirements; or egregious and/or knowing violations of Negotiation Program requirements.

Broadly, CMS is establishing a structure for enforcement actions that:

1. Is within CMS' statutory authority,
2. Is not punitive in response to immaterial or other instances of noncompliance that are not substantive,
3. Can be applied consistently across applicable instances of Primary Manufacturer noncompliance, and
4. Facilitates the ability to successfully engage in all components of the negotiation process within the established statutory timeframes.

This revised guidance addresses violations by a Primary Manufacturer for failure to ensure access to a price for a selected drug less than or equal to the MFP, violation of terms of the Agreement, and provision of false information as related to the aggregation rule of the Small Biotech Exception and the Biosimilar Delay Rule. This revised guidance does not address failure to pay a rebate for a biological product pursuant to section 1192(f)(4) of the Act, as this topic will be addressed in future guidance. CMS provides details about the process for CMP imposition in section 100.4 of this revised guidance.

100.1 Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP
In accordance with section 1197(a) of the Act, CMS may impose a CMP on a Primary Manufacturer of a selected drug that has entered into an Agreement with CMS upon failure to provide access to a price that is less than or equal to the MFP to MFP-eligible individuals dispensed the selected drug and to pharmacies, mail order services, or other dispensers with respect to MFP-eligible individuals who are dispensed the selected drug, including the failure to do so in connection with sales of the selected drug by a Secondary Manufacturer. CMS will be monitoring the WAC in relation to other pricing metrics. Upon discovery and confirmation of a failure to make the MFP available, CMS will send the Primary Manufacturer a Notice of Potential Noncompliance that will include information on the potential violation and an opportunity for corrective action. CMS will establish an informal process in which the Primary Manufacturer will have 10 business days to respond to the Notice of Potential Noncompliance to provide additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration. CMS will consider the materials

provided by the Primary Manufacturer when determining the Primary Manufacturer's CMP liability.

If the Primary Manufacturer fails to ensure access to a price less than or equal to the MFP, the statute provides for a CMP equal to 10 times the amount equal to the product of the number of units of such drug so dispensed (during such year) and the difference between the price for such drug made available (for such year by such manufacturer) to MFP-eligible individuals and the MFP for such drug for such year. For the purposes of calculating this CMP, CMS will use the amount that is equal to the required pass through of the MFP described in section 40.4 of this revised guidance. As described in section 40.5 of this revised guidance, CMS will monitor for compliance and audit, as needed, to ensure that the MFP or a price lower than the MFP is being made available for the selected drug.

100.2 Violations of the Agreement

Pursuant to section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into an Agreement with CMS under section 1193 of the Act that fails to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program pursuant to section 1193(a)(5) or fails to provide the information required under section 1193(a)(4) may be subject to a CMP of $1,000,000 for each day of such violation. In applying CMPs for Primary Manufacturer violations of the Agreement, CMS intends to use discretion such that CMPs are reserved for instances of substantive noncompliance. Examples of such violations are shown in the table below. Note that these examples are not an exhaustive list of violations that could warrant CMPs. CMS reserves the authority to issue CMPs for other violations as required to effectively administer and monitor the Negotiation Program.

Category	Example of Substantive Violations
Manufacturer Information Submission	• Failure to submit data required under section 1194(e)(1) of the Act, including failure to engage in requested corrective action to mitigate such failures. • Omissions or inaccuracies of manufacturer-submitted information that is critical to the negotiation processes (e.g., non-FAMP data from the Primary Manufacturer, including non-FAMP data for a selected drug sold by any Secondary Manufacturer(s), required for ceiling calculation) or other efforts to administer or monitor the Negotiation Program (e.g., information requested during an audit), including failure to engage in requested corrective action to mitigate such omissions or inaccuracies. • Submission of false information that interferes with the negotiation process (e.g., submission of false data on unit costs of production). • Knowing submission of false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) for the Small Biotech Exception. • Knowing provision of false information under procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Biosimilar Delay.
MFP Availability	• Failure to make the MFP available to MFP-eligible individuals, and to pharmacies, mail order services, or other dispensers (see section 100.1 of this revised guidance) • Failure to process timely and complete reimbursement under a retrospective reimbursement structure as described in section 40.4 of this revised guidance.

As an example of when CMS would impose a CMP, consider the following. As described in section 40.2 of this revised guidance, information on non-FAMP for each applicable quarter (as described in section 50.1.1 of this revised guidance) for each NDC-11 of the selected drug for the applicable period will be due to CMS as part of the Negotiation Data Elements ICR no later than October 2, 2023 for initial price applicability year 2026. If the Primary Manufacturer fails to timely submit the required non-FAMP information, including the non-FAMP information for each NDC-11 of a selected drug for which there is a Secondary Manufacturer, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the applicable submission deadline (e.g., October 3, 2023 for initial price applicability year 2026) as the first day of violation with each additional day of violation thereafter counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. In the event a manufacturer never provides the required information, the daily CMP will continue to accrue until the end of the negotiation period (i.e., the final deadline for reaching an agreed upon MFP). Upon reaching that deadline, the manufacturer may also be subject to a potential excise tax for failing to reach an agreed upon MFP pursuant to 26 U.S.C. § 5000D(b)(2).

CMS may require additional information to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act. When applicable, CMS will provide a written request to the Primary Manufacturer with details for such requests, including a date by which any requested information must be submitted. CMS is committed to providing Primary Manufacturers with reasonable timeframes to accommodate these information requests. CMS will consider written requests for deadline extension submitted no later than three calendar days prior to the initial deadline. Extension requests must include a reasonable basis for requiring the extension as determined by CMS. Only one extension, if applicable, will be granted for each request. Manufacturers that fail to comply with requests for information required to administer or monitor compliance with the Negotiation Program on or before the due date may be subject to a CMP.

In the event the manufacturer does not meet the final established deadline to provide the requested information and CMS determines a CMP is warranted, the CMP will begin to accrue beginning on the day after the due date. For example, if CMS requests information for monitoring purposes by November 15, 2027, day one of the violation would be November 16, 2027. Each additional day of violation thereafter will be counted until the day the Primary Manufacturer provides the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement. The CMP will not include the day the information is submitted. Because the day of data submission is not included in CMP calculation, should a Primary Manufacturer submit the requested information on the day after the deadline, no CMP will be imposed.

To facilitate program operations and support manufacturer compliance, CMS will provide the Primary Manufacturer with: (1) written reminders of impending submission deadlines, including warning of potential liability for a CMP for submission violations; and (2) Notification of Potential Noncompliance, if applicable, and the applicable next steps (see, for example, sections

40.2.3 and 100.1 of this revised guidance). If CMS determines a violation warrants a CMP, CMS will follow the procedures outlined in section 100.4 of this revised guidance to notify the Primary Manufacturer and initiate the CMP process.

A Primary Manufacturer that submits false Information that is required under the Agreement and interferes with the administration of the Negotiation Program will be out of compliance with the requirement to submit information and may be subject to this CMP. In instances of a Primary Manufacturer submitting false information that is required under the Agreement, CMS will determine the number of days in which the Primary Manufacturer is in violation of the Agreement by counting the day after the established deadline for submission of information under the Agreement as the first day of violation with each additional day of violation thereafter counted until the day the Primary Manufacturer provides a complete and accurate submission of the required information to CMS, the selected drug ceases to be a selected drug, or the Primary Manufacturer terminates the Agreement.

100.3 Provision of False Information Related to the Small Biotech Exception and the Biosimilar Delay Rule

In accordance with section 1197(d) of the Act, if CMS determines that any manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(d)(2)(B) for the Small Biotech Exception, such manufacturer shall be subject to a CMP equal to $100,000,000 for each item of such false information. Likewise, if CMS determines that any Biosimilar Manufacturer knowingly provides false information under the procedures to apply the aggregation rule in section 1192(f)(1)(C) of the Biosimilar Delay, such manufacturer shall be subject to a CMP equal to $100,000,000 for each item of such false information.

CMS adopts a standard for "knowingly" that conforms with the Office of the Inspector General definition at 42 C.F.R. § 1003.110 in the application of other CMPs. Knowingly means that a manufacturer, for purposes of section 1197(d) of the Act for the Small Biotech Exception or a Biosimilar Manufacturer under section 1192(f)(1)(c) for the Biosimilar delay: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. Upon identifying instances of knowing submission of false information under either of these provisions, CMS will provide the Manufacturer with a CMP Notification detailing the final CMP amount and the basis for that amount, requesting payment, outlining the payment process, outlining the available appeals process, and establishing applicable deadlines for resolution.

100.4 Notice and Appeal Procedures

Where CMS makes a determination to impose a CMP, CMS will provide a written CMP Notification that the manufacturer has engaged in a substantive compliance violation and is subject to a CMP. As required by section 1128A of the Act, the CMP Notification will include the following:

- A description of the basis for the determination;
- The basis for the penalty;
- The Primary Manufacturer's right to a hearing (see below); and

- Information about where to file the request for a hearing.

In applicable cases (e.g., failure to provide required information), CMS will note the commencement date for a CMP accrual and alert the manufacturer that the daily CMP will continue to accrue until the period of noncompliance ends. CMS will send monthly noncompliance notices to the manufacturer during the noncompliance period to include the total amount of CMP accrued to date, the amount that will continue to accrue should the violation continue, and required actions on the part of the Primary Manufacturer to mitigate the noncompliance period (e.g., submission of required information), if applicable.

To operationalize the CMP appeal process in the Negotiation Program, CMS is adopting the existing procedures as codified in 42 C.F.R. section 423 subpart T: Appeal Procedures for Civil Money Penalties (see § 423.1000 through § 423.1094) that currently apply to Part D sponsors and to manufacturers under the Coverage Gap Discount Program. Pursuant to this appeals process, the manufacturer will have 60 calendar days from the date of receipt of the CMP Notification to request a hearing (§ 423.1020). The date of receipt is defined as the calendar day following the day on which the CMP Notification is issued. If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act and operationalized by 42 C.F.R. § 423 Subpart T will apply. As set forth in section 1128A(f), if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP funds will be deposited in accordance with section 1128A(f).

The CMP amount will cease to accrue once the manufacturer has demonstrated compliance with the requirement(s) at issue in the relevant CMP Notification. Following the end of the noncompliance period, and at the conclusion of any appeals process initiated by the Primary Manufacturer within 60 days of the CMP Notification, CMS will issue the final CMP Notification. As required by section 1128A of the Act, the final notification will add the following to the information included in the initial CMP Notification and monthly noncompliance notices:

- The final amount of the penalty;
- The date the penalty is due; and
- Instructions for submitting the CMP payment.

110. Part D Formulary Inclusion of Selected Drugs

In accordance with section 1860D-4(b)(3)(I) of the Act, Medicare Part D plans shall include each covered Part D drug that is a selected drug under section 1192 of the Act on Part D formularies during contract year 2026 and all subsequent years for which the MFP of the selected drug is in effect during the price applicability period.[75] Because the selected drug includes all dosage forms and strengths to which the MFP applies for initial price applicability year 2026, the statute requires that all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect be included on formulary. For contract year 2026, CMS will not implement explicit tier placement or utilization management requirements that

[75] As required by section 1860D-4(b)(3)(I)(ii) of the Act, nothing shall prohibit a Part D sponsor from removing a selected drug from a formulary if such removal would be permitted under 42 C.F.R. § 423.120(b)(5)(iv) (or any successor regulation).

apply uniformly across selected drugs in all formularies, but intends to apply the process described below.

While CMS understands that not all selected drugs and drug classes will present Part D sponsors and their Pharmacy & Therapeutics Committees with the same formulary considerations and might not warrant the same formulary placement in all situations, CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.

CMS reminds Part D sponsors of the existing statutory and regulatory restrictions on formulary design. Sections 1860D-2(b)(2)(B) and 1860D-4(c)(1)(A) of the Act permit Part D sponsors to use formularies and tiered cost sharing in their benefit design, subject to certain limitations, and requires them to have a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate. Under section 1860D-11(e)(2)(D)(i) of the Act, CMS may approve a prescription drug plan only if the agency "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." In addition, 42 C.F.R. § 423.272(b)(2)(i) states: "CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Furthermore, 42 C.F.R. § 423.120(b)(2)(iii) requires each Part D plan formulary to "include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines." In addition, 42 C.F.R. § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must "base clinical decisions on the strength of scientific evidence and standards of practice." CMS maintains a robust clinical formulary review process to ensure that all Medicare Part D plans meet these and other applicable requirements. CMS reviews all formularies annually to ensure that each formulary passes the agency's clinical review criteria, which includes comprehensive evaluation of tier placement and all utilization management restrictions and criteria.

Given CMS' statutory obligation to monitor Medicare Part D plans' compliance with all applicable formulary requirements, CMS will use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers, (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class, (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP (i.e., step therapy), or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

For this review, CMS will consider class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action. Specifically, as part of the contract year 2026 Part D formulary review and approval process, CMS will expect Part D sponsors to provide a reasonable justification to support the submitted plan design that includes

any of the practices noted above during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will only approve a Part D plan bid submitted by a Part D sponsor if the plan benefit package complies with those requirements.

120. Application of Medicare Part B and Part D Prescription Drug Inflation Rebate Programs to Selected Drugs

This section of the guidance describes the application of Medicare Part B and Part D inflation rebates to selected drugs. As background, section 11101 of the IRA added a new section 1847A(i) to the Act to require that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Likewise, section 11102 of the IRA added a new section 1860D-14B to the Act, which requires that manufacturers of Part D rebatable drugs pay inflation rebates to Medicare for certain Part D rebatable drugs based on specific requirements and formulas.[76]

Given that initial price applicability year 2026 is limited to drugs for which there is Part D utilization, this revised guidance describes the interaction between the Negotiation Program and the Part D inflation rebate program. CMS will address the application of Part B inflation rebates to selected drugs in future guidance for initial price applicability year 2028.

The Part D drug inflation rebate program is applicable to certain drugs that meet the definition of a Part D rebatable drug and are dispensed under Part D and covered and paid for by Part D plans for each 12-month applicable period, starting with the applicable period beginning October 1, 2022. These rebates are paid by manufacturers to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

The Part B and Part D inflation rebate programs apply to selected drugs, regardless of the status of the drug as a selected drug. Alternatively said, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Part B and Part D inflation rebate program, as applicable. However, when a selected drug is no longer considered to be a selected drug, certain components of the applicable rebate amount formula are recalculated as discussed further below.

[76] CMS published initial guidance on both Part B and Part D inflation rebates on February 9, 2023, which includes more specific details on the operation of the Part B and Part D inflation rebate programs. See: https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf and https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.

The Part D inflation rebate calculation is based on changes in the AMP over time.[77] MFP is excluded from AMP and thus does not affect the rebate calculation.[78]

The statutory formula to determine the Part D drug inflation rebate amount owed by manufacturers for each Part D rebatable drug consists of various components, including the calculation of a benchmark period manufacturer price. This "benchmark period manufacturer price" is calculated based on a "payment amount benchmark period" for each Part D rebatable drug (established at section 1860D-14B(g)(3) of the Act for drugs first approved or licensed on or before October 1, 2021 and at section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021), and a "benchmark period CPI-U"[79] for each Part D rebatable drug (established at section 1860D-14B(g)(4) of the Act for drugs first approved or licensed on or before October 1, 2021 and section 1860D-14B(b)(5)(A) for drugs first approved or licensed after October 1, 2021). The payment amount benchmark period is the basis for the calculation of the benchmark period manufacturer price. The benchmark period manufacturer price is based on a weighted AMP for the quarters in that period.

For the period of time before a Part D rebatable drug is a selected drug, and during the time it is a selected drug, CMS will calculate the Part D inflation rebate amount, if applicable, based on the Part D rebatable drug's applicable payment amount benchmark period and benchmark period CPI-U, which is determined based on when the drug is first approved or licensed, as noted above. However, the statute at section 1860D-14B(b)(5)(C) specifies a different "payment amount benchmark period" and "benchmark period CPI-U" for each Part D rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, the payment amount benchmark period will be reset as the last year that begins during such price applicability period for such selected drug, and the benchmark period CPI-U is established as the January of the last year beginning during such price applicability period.

[77] Section 1860D-14B(g)(6) of the Act defines AMP to have the meaning, with respect to a Part D rebatable drug of a manufacturer, given in section 1927(k)(1) with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. Section 1927(k)(1) defines AMP, with respect to a covered outpatient drug of a manufacturer for a rebate period, to mean the average price paid to the manufacturer for the drug in the United States by (i) wholesalers for drugs distributed to retail community pharmacies, and (ii) retail community pharmacies that purchase directly from the manufacturer, subject to certain exclusions.

[78] Section 1927(k)(1)(B)(i)(VI), as amended by section 11001(b)(3) of the Inflation Reduction Act.

[79] CPI-U refers to the Consumer Price Index for all urban consumers (United States city average).

Appendix A: Email Template for Biosimilar Manufacturer to Indicate Intent to Submit an Initial Delay Request for Initial Price Applicability Year 2026

Email subject line:
Biosimilar Delay: Notice of Intent to Submit Initial Delay Request for Initial Price Applicability Year 2026

Body of email:
Dear CMS,

I, an authorized representative of [insert manufacturer name], am notifying CMS that my company is the manufacturer of a biosimilar biological product and we anticipate the reference product for our biosimilar biological product will be included in a negotiation-eligible drug with respect to initial price applicability year 2026 for the Medicare Drug Price Negotiation Program. My company reasonably believes the market entry of our biosimilar biological product meets the criteria for the special rule to delay selection and negotiation of the negotiation-eligible drug, described in section 1192(f) of the Social Security Act. Therefore, I am notifying CMS of my company's intent to request that CMS delay the inclusion of the negotiation-eligible drug that includes the reference product for our biosimilar biological product on the selected drug list for initial price applicability year 2026.

As part of this notification, I am providing the following information:

My job title:	[insert]
My email address:	[insert]
My phone number:	[insert]
My company's mailing address:	[insert]
My company's biosimilar biological product name:	[insert]
Product name of the reference product for my company's biosimilar biological product	[insert]

Signed,
[Insert name of authorized representative]

Appendix B: Template for the Initial Delay Request Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act), to negotiate maximum fair prices (MFPs)[80] for selected drugs. Under section 1192(f) of the Act (the "Biosimilar Delay"), the manufacturer of a biosimilar biological product ("Biosimilar Manufacturer" of a "Biosimilar") may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug (as defined in section 1192(d) of the Act) that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a "Reference Drug") on the selected drug list for a given initial price applicability year. The Biosimilar Manufacturer eligible to submit the request is the holder of the BLA for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA for the Biosimilar that has been submitted for review by FDA.

Please refer to the memo titled "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" (Initial Negotiation Program Guidance) for additional details regarding the implementation of the Biosimilar Delay for initial price applicability year 2026. This form serves as the template that a Biosimilar Manufacturer may complete to submit an Initial Delay Request with respect to initial price applicability year 2026.

Submission of the email described in that memo indicating the Biosimilar Manufacturer's intention to submit an Initial Delay Request for initial price applicability year 2026 and receipt of the fillable Initial Delay Request form template and request-specific Box folder should occur prior to completing this form.

Instructions

- Initial Delay Requests that are incomplete or not timely submitted will not be accepted. For an Initial Delay Request to be timely for initial price applicability year 2026, the Biosimilar Manufacturer must submit a complete Initial Delay Request to CMS no later than 11:59 pm PT on May 22, 2023. CMS will deem an Initial Delay Request to be complete if it includes a complete Initial Delay Request form using this fillable template and the following documentation:
    - All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

[80] In accordance with section 1191(c)(3) of the Social Security Act ("the Act"), maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year.

- The manufacturing schedule for the Biosimilar submitted to the FDA during its review of the application for licensure under section 351(k) of the PHS Act, to the extent available; and
- Disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, to the extent available.

- The data entry component of this submission should be completed by an individual authorized by the Biosimilar Manufacturer.
- The certification of the Initial Delay Request should be executed by (1) the chief executive officer (CEO) of the Biosimilar Manufacturer, (2) the chief financial officer (CFO) of the Biosimilar Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

CMS is relying on the fullness, accuracy, and completeness of the Biosimilar Manufacturer's submission to determine whether to approve the Initial Delay Request for initial price applicability year 2026. If the Biosimilar Manufacturer submits an Initial Delay Request that is not timely, complete, and accurate, the submission may adversely affect the Negotiation Program, including the process for selecting drugs for negotiation for initial price applicability year 2026.

Section 1: Identifying information

Identifying information for Biosimilar Manufacturer

Q1. Complete the following table with identifying information for the Biosimilar Manufacturer.

Field	Response
Entity Type	☐ Biosimilar Manufacturer
Entity name	
Employer Identification Number (EIN(s))	
Address	
Unique Identifier Assigned by CMS (P-number)	
Labeler Code(s)	

Identifying information on Biosimilar

Q2. Complete the following table with identifying information for the Biosimilar.

Field	Response
Product Name	

Active Ingredient	
NDC-9(s) (if applicable)	[optional, only if available]

Q3. List all applications for licensure for the Biosimilar under 351(k) of the Public Health Service (PHS) Act regardless of status (i.e., including applications that are approved, accepted for review, and submitted but not yet accepted for review). Leave approval date blank if license has not been approved.

Add additional rows for each application

Application Number	Submission Number	Application status	Approval Date [if licensed]	Indication	Dosage Form and Strength	Licensure planned before September 1, 2025?	Marketing planned before September 1, 2025?
nnnnnn	nnn	[Approved, Accepted for Review, Submitted]	MM/DD/ YYYY	Text	Text	[Yes/No]	[Yes/No]

Identifying information on Reference Product

Q4. Complete the following table with identifying information for the reference product for the Biosimilar.

Field	**Response**
Product Name	
Active Ingredient	
NDC-9(s)	

Q5. List the Biologic License Application (BLA) approved by the Food and Drug Administration (FDA) under section 351(a) of the PHS Act for the reference product for the Biosimilar.

Application Number	Submission Number	Approval Date	Indication	Dosage Form and Strength	Sponsor
nnnnnn	nnn	MM/DD/ YYYY	Text	Text	Text

Identifying information on Reference Manufacturer

Q6. Complete the following table with identifying information for the Reference Manufacturer.

Field	**Response**
Entity Type	☐ Reference Manufacturer
Entity name	

Employer Identification Number (EIN)	*[Optional, only if known]*
Address	*[Optional, only if known]*
Unique Identifier Assigned by CMS (P-number)	*[Optional, only if known]*
Labeler Code(s)	*[Optional, only if known]*

Section 2: Attestations to Requirements for Granting an Initial Delay Request

In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not delay inclusion of a biological product on the list of selected drugs if the Biosimilar Manufacturer meets any of the statutory criteria for an excluded manufacturer. Questions 7 through 9 address whether the Biosimilar Manufacturer is an excluded manufacturer.

Q7. Relationship between Biosimilar Manufacturer and Reference Manufacturer: In accordance with section 1192(f)(2)(D)(iv) of the Act, CMS will not approve an Initial Delay Request if the Biosimilar Manufacturer is the same as the Reference Manufacturer or is treated as being the same as the Reference Manufacturer based on the aggregation rule in section 1192(f)(1)(C) of the Act. This aggregation rule provides, "all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer" for purposes of the Biosimilar Delay. Further, section 1192(f)(1)(C) of the Act establishes that "the term 'partnership' means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on" by two or more parties for the purposes of the Biosimilar Delay.

Read the following statement and check the box if accurate:

I confirm consistent with sections 1192(f)(1)(C) and 1192(f)(2)(D)(iv) of the Act that the Biosimilar Manufacturer submitting this request is not the same or is not treated as being the same as the Reference Manufacturer.	☐

Q8. Incentives: In accordance with section 1192(f)(2)(D)(iv)(II)(aa) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(aa) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that requires or incentivizes the Biosimilar Manufacturer to submit this or any other Initial Delay Request.	☐

Q9. Quantity Restriction: In accordance with section 1192(f)(2)(D)(iv)(II)(bb) of the Act, CMS will not approve any Initial Delay Request submitted by a Biosimilar Manufacturer that has entered into an agreement with the Reference Manufacturer that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(2)(D)(iv)(II)(bb) of the Act that the Biosimilar Manufacturer submitting this request has not entered into an agreement with the Reference Manufacturer named in this request that restricts the quantity, either directly or indirectly, of the Biosimilar that may be sold in the United States over a specified period of time.	☐

In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed and marketed before September 1, 2025. Questions 10 and 11 are relevant for this determination.

Q10. Licensure: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be licensed before September 1, 2025. For the purposes of this Initial Delay Request, 'licensed' means approved by the FDA under section 351(k) of the PHS Act.

Select the following option that best describes the current licensure status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the Biosimilar has been licensed.	☐
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and the FDA has accepted such application for review.	☐
(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act and has not received a determination from FDA that such application has been accepted for review.	☐
(D) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar Manufacturer has not submitted an application for licensure of the Biosimilar under section 351(k) of the PHS Act.	☐

Q11. Marketing: In accordance with section 1192(f)(1)(A) of the Act, CMS will only approve an Initial Delay Request for initial price applicability year 2026 if CMS determines there is a high likelihood that the Biosimilar will be marketed before September 1, 2025.
Select the following option that best describes the current marketing status of the Biosimilar as of the submission of this Initial Delay Request:

(A) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar is currently marketed.	☐
(B) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed but the Biosimilar Manufacturer expects it to be marketed by September 1, 2025.	☐

(C) I confirm consistent with section 1192(f)(1)(A) of the Act that the Biosimilar has not yet been marketed and the Biosimilar Manufacturer does not expect it to be marketed by September 1, 2025.	☐

Section 3: Supporting Documentation

Q12. Manufacturing schedule: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, the manufacturing schedule for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation - Manufacturing schedule' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload the manufacturing schedule(s) for the Biosimilar submitted to the FDA for each application listed in Q3.

Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure is available for submission.	☐
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS the manufacturing schedule(s) for the Biosimilar submitted to the FDA during its review of the Biosimilar's application for licensure.	☐

Q13. Disclosures: In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include, to the extent available, disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Disclosures' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such disclosures.
Read the following statements and check the boxes if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that disclosures (in filings by the Biosimilar Manufacturer with the Securities and Exchange Commission required under section12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the Biosimilar Manufacturer that are typical of the normal course of business before marketing of a biosimilar biological product) that pertain to the marketing of the	☐

Biosimilar, or comparable documentation that is distributed to the shareholders of privately held companies, are available for submission.	
I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all such disclosures.	☐

Q14. Agreements:
In accordance with section 1192(f)(1)(B)(ii)(I) of the Act, an Initial Delay Request must include all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Further, in accordance with section 1192(f)(3)(B) of the Act, CMS will consider such information in determining whether there is clear and convincing evidence that the Biosimilar will be marketed.

Using the 'Supporting Documentation – Agreements' subfolder within the Box folder that CMS shared for the purposes of this Initial Delay Request, upload all such agreements.

Read the following statement and check the box if accurate:

I confirm consistent with section 1192(f)(1)(B)(ii)(I) of the Act that I have submitted to CMS all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.	☐

Section 4: Certification

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including to determine whether CMS should delay the selection of a biological product that would, absent this request, be included on the selected drug list for initial price applicability year 2026, as described in section 1192(f) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes []
No []

Contact Information

Field	Response
Name of the Person Responsible for the Submission	
Title	
Telephone	
Email	
Signature	
Date	

Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

For the purposes of describing the data at sections 1194(e)(1), 1194(e)(2), and 1193(a)(4)(A) of the Act to be collected for use in the Negotiation Program, as described in sections 40.2, 50.1, and 50.2 of this revised guidance and the Negotiation Data Elements Information Collection Request (ICR), CMS adopts the following definitions and standards.

General

- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment. If a Primary Manufacturer uses a cost of capital below 8.1 percent, that amount should be used.

Non-FAMP

- Non-FAMP: Section 1194(c)(6) of the Act defines "average non-Federal average manufacturer price" as the average of the non-FAMP (as defined in section 8126(h)(5) of title 38 of the U.S. Code) for the four calendar quarters of the year involved.[81] For initial price applicability year 2026, these are the quarters of 2021. When there are less than 30 days of commercial sales data for all NDC-11s of the selected drug in calendar year 2021, the applicable year will be the first full calendar year following market entry of such drug. When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) for a given NDC-11 of such drug, the non-FAMP reported by the manufacturer to CMS should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2023 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585. Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS.
- Non-FAMP unit: Non-FAMP unit is the package unit as described in 38 U.S.C. § 8126(h)(6).
- Non-FAMP dosage form unit: The non-FAMP dosage form unit is the dosage form of the NDC that is reported in the "Dose form" field of the Excel workbook used by the Office of Pharmacy Benefits Management Services at the VA to collect non-FAMP information.

Research and Development (R&D) Costs

R&D costs mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications of a drug falling into the five categories below, and excluding (a) prior Federal financial support, (b) costs associated with applying for and receiving foreign approvals,

[81] The term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account— (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount. 38 U.S.C. § 8126(h)(5).

and (c) costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Acquisition Costs
2. R&D: Basic Pre-Clinical Research Costs
3. R&D: Post-Investigational New Drug (IND) Application Costs
4. R&D: Abandoned and Failed Drug Costs
5. R&D: All Other R&D Direct Costs

CMS is calculating recoupment of R&D costs using both the global and U.S. total lifetime net revenue for the selected drug:

6. Recoupment: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

The definitions and associated time periods for these terms are included below.

Definitions for 1. R&D: Acquisition Costs

- For the sole purpose of data collection under section 1194(e)(1)(A) of the Act, acquisition costs are defined as costs associated with the Primary Manufacturer's purchase from another entity of the rights to hold previously approved or future NDA(s) / BLA(s) of the selected drug.

Definitions for 2. R&D: Basic Pre-Clinical Research Costs

- Basic pre-clinical research costs are defined as all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses (defined below).
- For each indication of the selected drug, the basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) to the day before the last IND application for that indication of the selected drug went into effect.[82, 83] The basic pre-clinical research period may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications that went into effect, use the date of the first IND application that went into effect as the end date for the 52-month period.[84]

[82] CMS acknowledges that the exact date of initial discovery might not be known, but manufacturers should use their best estimate.

[83] For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug, use the earliest date of acquisition for any NDA / BLA of the selected drug.

[84] CMS believes that 52 months represents a solid average across studies. For example, one study reported that the pre-clinical phase takes 52 months on average. See DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 2003, https://fds.duke.edu/db?attachment-

- Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect basic pre-clinical research costs and relevant general and administrative costs are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[85, 86] For example, if the *direct* pre-clinical research costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then *indirect* costs should be allocated proportionally, thus for the selected drug they should be 10 percent of the total spending on *indirect* pre-clinical research costs during that time period.

Definitions for 3. R&D: Post-Investigational New Drug (IND) Application Costs

- Post-IND costs are defined as all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication. Post-IND costs also include all direct costs associated with completed FDA-required, post-marketing trials that are conducted after the FDA has approved a product. Post-IND costs exclude FDA-required, post-marketing trials that were not completed.
- Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period. Direct post-IND costs also include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed FDA-required, post-marketing trial.

25--1301-view-168. Another study estimated that the pre-clinical phase can take 31 months on average. See DiMasi, J, Grabowski, H, Hansen, R. Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, 2016, as cited by the Congressional Budget Office (CBO) in Research and Development in the Pharmaceutical Industry, April 2021, https://www.cbo.gov/publication/57126. Other estimates have found that the pre-clinical phase ranges from three to six years. See PhRMA, "Biopharmaceutical Research & Development: The Process Behind New Medicines," 2015, http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

[85] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA.* 2020;323(9):844–853. doi:10.1001/jama.2020.1166

[86] Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html.

- The post-IND period begins on the day the IND went into effect for the first FDA-approved indication for the selected drug through the date when the last FDA-required post-marketing trial was completed for the selected drug.

Definitions for 4. R&D: Abandoned and Failed Drug Costs

- Failed or abandoned product costs include a sum of the portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
- Failed or abandoned product costs include a portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials.
    - Direct research expenses are costs that can specifically be attributed to the discovery and pre-clinical development of the drug.
    - Direct research expenses include personnel (compensation for investigators and staff) researching the drug, materials for conducting basic pre-clinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned product costs include a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
    - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
    - Direct post-IND costs include IRB review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting dosing and clinical trials for the drug.

Definitions for 5. R&D: All Other R&D Direct Costs

- All other R&D direct costs are any other allowable costs that do not align with R&D definitions 1-4. For example, other R&D direct costs may include direct costs associated with conducting FDA-required post-marketing trials that were not completed. No additional definitions adopted.

Definitions for 6. Global and U.S. Total Lifetime Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer's global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.

Definitions for 6a. Global, including U.S., Total Lifetime Net Revenue for the Selected Drug

- Global, total lifetime net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

- Global, total lifetime net revenue period is defined as the date the drug or biologic was first sold anywhere globally through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Definitions for 6b. U.S. Lifetime Net Revenue for the Selected Drug

- U.S. lifetime net revenue for the selected drug is defined as the direct sales and payments from U.S. entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
- U.S. lifetime net revenue period is defined as the date the drug or biologic was first sold in the U.S. through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If U.S. lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Current Unit Costs of Production and Distribution

- In accordance with section 1191(c)(6) of the Act, the term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)[87]: each (EA), milliliter (ML), or gram (GM). The unit reported must be specified for each of the NDC-11s of the selected drug. Selections of EA, ML or GM must be made as follows:
    - "EA" is used when the product is dispensed in discrete units. These products are not measured by volume or weight. The Billing Unit of "EA" is also used to address exceptions where "GM" and "ML" are not applicable. Examples of products defined as "EA" include, but are not limited to:
        - Tablets;
        - Capsules;
        - Suppositories;
        - Transdermal patches;
        - Non-filled syringes;
        - Tapes;
        - Devices/Digital Therapies;

[87] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

- Blister packs;
- Oral powder packets;
- Powder filled vials for injection;
- Kits;[88] and
- Unit-of-use packages of products other than injectables with a quantity less than one milliliter or gram should be billed as "one each," for example, ointment in packets of less than 1 gram or eye drops in dropperettes that contain less than 1 ML.

  - "ML" is used when a product is measured by its liquid volume. Examples of products defined as "ML" include, but are not limited to:
    - Liquid non-injectable products of 1 ML or greater;
    - Liquid injectable products in vials/ampules/syringes;
    - Reconstitutable non-injectable products at the final volume after reconstitution except when they are in powder packets; and
    - Inhalers (when labeled as milliliters on the product).
  - "GM" is used when a product is measured by its weight. Examples of products defined as "GM" include, but are not limited to:
    - Creams (of 1 GM or greater);
    - Ointments (of 1 GM or greater); and
    - Inhalers (when labeled as GM on the product).[89]

- Costs of <u>production</u> are defined as all (direct and allocation of indirect) costs related to:
  - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
  - Formulation and preparation of the finished drug product;
  - Quality control and testing of the drug; and
  - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug.
- Costs of <u>distribution</u> are defined as all (direct and allocation of indirect) costs related to:
  - Packaging and packaging materials;
  - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
  - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
  - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- Current unit costs of production and distribution of the selected drug are defined to include:

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[88] Kits are defined as products that contain one of the following: (1) at least two distinct items with different billing units; (2) one product packaged with medicated or unmedicated swabs, wipes and/or cotton swabs/balls; or (3) meters packaged with test strips.

[89] See: https://standards.ncpdp.org/Standards/media/pdf/BUS_fact_sheet.pdf. *Permission is hereby granted to any organization to copy and distribute this material as long as this copyright statement is included, the contents are not changed, and the copies are not sold.*

  - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
  - Average unit costs during the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year);
  - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
  - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third parties (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
  - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug are defined not to include:
  - R&D costs; and
  - Marketing costs.
- "Marketing costs" are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, and other paid promotion.

Prior Federal Financial Support

For the purposes of describing prior federal financial support for novel therapeutic discovery and development to be collected for use in the Negotiation Program with respect to the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this revised guidance, CMS adopts the definitions described in this subsection.

- "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug.
- "*Prior* Federal financial support" refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, whichever is later, to the day through the date the most recent NDA / BLA was approved for the selected drug.

Patents, Exclusivities, and Approvals

- CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:
  - All patents issued by the United States Patent and Trademark Office (USPTO), as of September 1, 2023, both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected

drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
    - All patents related to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
    - All patent applications related to the selected drug that are pending issuance by the USPTO.
    - Patents and patent applications related to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book[90]; utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug; and design patents that, for example, claim a design on the packaging of the selected drug.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays and prohibitions on the approval of competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[91]
    - New Chemical Entity Exclusivity (NCE);[92]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[93]
    - New Clinical Investigation Exclusivity (NCI);[94]
    - Pediatric Exclusivity (PED);[95] and
    - Reference Product Exclusivity for Biological Products.[96]
- Active and pending FDA applications and approvals includes all applications for approval under section 505(c) of the FD&C Act or sections 351(a) of the PHS Act, including those not yet decided.

Market Data and Revenue and Sales Volume Data

- Wholesale Acquisition Cost (WAC) unit price: The manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC-11 level.

[90] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.
[91] Section 527 of the Federal Food, Drug and Cosmetic (FD&C) Act.
[92] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[93] Section 505E(a) of the FD&C Act.
[94] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[95] Section 505A(b) & (c) of the FD&C Act.
[96] Section 351(k)(7) of the PHS Act.

- National Council of Prescription Drug Programs (NCPDP) Billing Unit Standards: The three NCPDP Billing Unit Standards (BUS)[97] are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Medicaid best price: The Medicaid best price is defined in 42 C.F.R. § 447.505(a). The Medicaid best price is reported at the NDC-9 level.
- Average manufacturer price (AMP) unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Federal supply schedule (FSS) price: The price offered by the VA in its FSS program, by delegated authority of the General Services Administration.[98] The FSS price is reported at the NDC-11 level.
- Big Four price: The Big Four price is described in 38 U.S.C. § 8126. The Big Four price is reported at the NDC-11 level.
- U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price is reported at the NDC-11 level.
- U.S. commercial average net unit price─ without patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price net of manufacturer-run patient assistance programs that provide financial assistance such as coupons and co-payment assistance or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price─ without patient assistance program is reported at the NDC-11 level.
- U.S. commercial average net unit price─ best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any

[97] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.
[98] See: https://www.fss.va.gov/index.asp.

Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price─ best is reported at the NDC-11 level.

Evidence About Alternative Treatments

- Therapeutic Alternative: A therapeutic alternative must be a pharmaceutical product that is clinically comparable to the selected drug. CMS will consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off-label to treat a given indication. CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on the subset of therapeutic alternatives that are most clinically comparable to the selected drug.
- Outcomes: Outcomes may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life. Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients, and patient-reported outcomes will also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered, including patient-centered outcomes when available, to the extent that these outcomes correspond with a direct impact on individuals taking the drug. The caregiver perspective will be considered when there is a direct impact on the individuals taking the selected drug or therapeutic alternative.
- Patient-centered outcome: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves.[99]
- Specific populations: Specific populations include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries including those that may experience disparities in access to care, health outcomes, or other factors when taking the selected drug that impact health equity.
- Health equity: The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[100]
- Unmet medical need: A drug or biological product may be considered to meet an unmet medical need if the drug or biological product treats a disease or condition in cases where no other treatment options exist or existing treatments do not adequately address the

[99] Source: ISPOR Plenary, Patrick (2013) via FDA's "Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders" (June 2020). See: https://www.fda.gov/media/139088/download.
[100] See: https://www.cms.gov/pillar/health-equity.

disease or condition.[101] Unmet medical need is determined at the time of submission of this information.

[101] CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" (May 2014) when considering if a drug addresses an unmet medical need for the purpose of the Negotiation Program.

Exhibit B

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
(hereinafter referred to as the "Agreement")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act ("the Act"), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program"), which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as "maximum fair price" in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on [Date]; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the

Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section 1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—
   i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and
   ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.

b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—
   i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and
   ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.

c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—
   i. maximum fair price eligible individuals, who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and
   ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.

d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price

applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;
ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and
iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.

e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.
f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—
   i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and
   ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.
g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.
b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.
c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.

b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.
c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.
d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.
e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.
f) In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.
g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.
h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.
i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations, or guidance.
j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement.
k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 1: Negotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
NEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program; and

WHEREAS, the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug in accordance with the negotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a price for the Selected Drug, as published by CMS in accordance with section 1195(a) of the Act and updated in accordance with sections 1195(b) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement;

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.

b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.

c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth

in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing below, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____ _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 2: Renegotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
RENEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program and agreed to such a price on [Date(s)]; and

WHEREAS, the Manufacturer and CMS have engaged in renegotiation of the price for the Selected Drug in accordance with the renegotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a renegotiated price for the Selected Drug, as published by CMS in accordance with section 1194(f)(4) of the Act and updated in accordance with sections 1194(f)(4) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement; and

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.
b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.
c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing this, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____ _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____

Exhibit C

Case 3:23-cv-04181-TLT-VKD Document 28-3 Filed 07/12/24 Page 285 of 308 Case 24-1820, Document: 28-3, Page: 285, Date Filed: 07/12/2024, PageID: 421

Drugs likely subject to Medicare negotiation, 2026-2028

Sean Dickson, JD, MPH; Inmaculada Hernandez, PharmD, PhD

Plain language summary

By 2028, Medicare will negotiate prices for 38 drugs dispensed in pharmacies and 2 drugs provided in physician offices. Medicare drug price negotiation will benefit patients with common diseases such as diabetes, cancer, respiratory conditions, or cardiovascular disease. Our list of drugs expected to be negotiated by Medicare shows patients, clinicians, and insurers which drugs will become more affordable for seniors in the next few years.

Implications for managed care pharmacy

Our list informs health plans of the drugs that will likely see major reductions in price and subsequently cost sharing under Medicare and identifies other top-spend drugs that will be ineligible for negotiation. This information will guide Part D benefit design, formulary placement, and insurer negotiations with manufacturers for discounts.

Author affiliations

West Health Policy Center, Washington, DC (Dickson); Division of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California, San Diego, La Jolla (Hernandez).

AUTHOR CORRESPONDENCE:
Inmaculada Hernandez, 1.858.822.6047;
inhernandez@health.ucsd.edu

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ABSTRACT

BACKGROUND: After the passage of the Inflation Reduction Act, Medicare will be able to negotiate drug prices starting in 2026. The Congressional Budget Office has estimated the total savings achieved each year for negotiation but has not publicly identified the drugs anticipated to be negotiated each year.

OBJECTIVE: To identify the drugs expected to be negotiated by Medicare in 2026-2028.

METHODS: We identify drugs expected to be negotiated by the Centers for Medicare & Medicaid Services in 2026-2028 based on the statutory criteria, Part B and Part D gross spending in 2020, and estimates of when a drug will be subject to generic or biosimilar competition. We also identify the reasons why other high-spend drugs will be ineligible for negotiation.

RESULTS: In 2026-2028, we estimate that Medicare will negotiate prices for 38 Medicare Part D drugs and 2 Part B drugs. Combined, the 40 products eligible for negotiation in 2026-2028 accounted for $67.4 billion in gross Medicare spending in 2020. Part D drugs eligible for negotiation in 2026-2028 include 7 inhalers, 8 antidiabetics, 5 kinase inhibitors, and 3 oral anticoagulants. In all but 5 cases, high-spend drugs ineligible for negotiation were disqualified because of generic or biosimilar competition.

CONCLUSIONS: Medicare drug price negotiation has the potential to benefit Medicare beneficiaries across some of the most common disease states. By generating the list of drugs likely subject to Medicare negotiation in the initial years, we hope to provider researchers, policymakers, prescribers, and patient advocates with expectations on which drugs are expected to see reductions in beneficiary cost sharing.

Nearly 20 years after the creation of the Medicare Part D program, the Centers for Medicare & Medicaid Services (CMS) will be able to negotiate drug prices directly with manufacturers following the passage of the Inflation Reduction Act of 2022.[1] Under this new authority, CMS will apply negotiated maximum fair prices for selected small-molecule drugs that have been on the market for at least 9 years and for biologic therapies marketed for more than 13 years, although the negotiations begin 2 years before they are applied, making the age threshold 7 and 11 years, respectively. Drugs are only eligible if there is no marketed generic or biosimilar

Case 3:23-cv-04818-JNQ-DTD Document 28-3 Page 286 of 1308 Date Filed: 07/12/2024 PageID: 422

therapy, excluding authorized generics or authorized biosimilars. Drugs approved under an orphan drug application and that only have orphan indications for a single disease or condition will be ineligible for negotiation. Orphan drugs with indications for multiple diseases will, however, remain eligible for negotiation. CMS will negotiate prices on the highest gross spend 10 Part D drugs for implementation in 2026, 15 Part D drugs for 2027, and 15 drugs from across the Medicare Part B and D programs for 2028 (Medicare Part B covers provider-administered drugs, whereas Part D covers retail prescription drugs). From 2029 onward, 20 drugs from across the 2 Parts will be negotiated. In calculating gross spend, CMS includes dispensing fees for Part D drugs and add-on and bundled payments for Part B drugs.

Negotiated prices will remain in effect until the drug becomes ineligible because of generic or biosimilar competition, and the negotiated price will be capped at a certain discount based on the drug's age. Drugs marketed for 9-12 years will be subject to a minimum discount of 25%; drugs marketed 12-16 years face a minimum discount of 35%; and drugs marketed for more than 16 years must discount prices by at least 60%; however, prior to 2030, drugs marketed 12-16 years will only be subject to the 25% minimum discount. Drugs will become ineligible for negotiation when a generic or biosimilar version has been approved and marketed for at least 9 months prior to January 1 of the year in which negotiated prices would apply. The definition of generic or biosimilar marketing status relies on the determination of the US Food and Drug Administration (FDA).[2]

Two years prior to the implementation of negotiated prices, CMS will begin negotiation on the top eligible drugs based on age and generic/biosimilar availability by gross spend, although negotiation for 2026 will begin in 2023 under a timeline provided by CMS.[3] The Congressional Budget Office (CBO) has estimated the total savings achieved each year for negotiation (in 2026, $3.7 billion; 2027, $8.3 billion; 2028, $17.5 billion)[4] but has not publicly identified the drugs anticipated to be negotiated each year. To aid policymakers and practitioners, we leverage public data to project which specific drugs will likely be subject to negotiation from 2026-2028.

Methods

We identify drugs expected to be negotiated by CMS for benefit years 2026-2028 based on drug age, drug or biologic status, orphan drug status, Part B and Part D gross spending in 2020,[5,6] and estimates of when a drug will be subject to generic or biosimilar competition (loss of exclusivity [LOE]). Drug age, drug or biologic status, and orphan drug status were ascertained from the FDA website.[7] Part B and Part D gross spending in 2020 was obtained from the CMS spending dashboards, which report gross spending per product (inclusive of manufacturer discounts).[4,5] For drug products, we estimated LOE based on the latest expiration date of any drug substance or drug product patent listed in the Orange Book;[8] this was superseded by any publicly disclosed patent settlement date, for which we performed an online search for each product and generic or biosimilar competitors, as appropriate, and reviewed the most recent annual securities filings from each manufacturer. For biologics, we use estimated LOE from an expert report.[9] Notably, for a drug to be ineligible for negotiation because of competition, the generic or biosimilar must have been marketed at least 9 months prior to the year of implementation of negotiated prices. In other words, a reference drug with generic entry in June 2026 would remain eligible for negotiation until 2028.

In addition to our projections of drugs subject to negotiation, we report public information on the minimum discount percentage required by statute based on the drug's years on the market, Medicare gross spending on the drug in 2020 obtained from the dashboards,[5,10] and the CBO's estimated annual savings from negotiation.[4] Finally, we report all high-spend drugs that we excluded from the list of likely negotiated drugs and the reasons for exclusion.

Additional information: The study was not registered.

Results

For 2026, the top drugs projected for negotiation include anticoagulants Eliquis (apixaban) and Xarelto (rivaroxaban), oral antidiabetics Januvia (sitagliptin) and Jardiance (empagliflozin), the tumor necrosis factor inhibitor Enbrel (etanercept), and the inhalers Symbicort (budenoside/formoterol) and Breo Ellipta (fluticasone/vilanterol) (Table 1). Three cancer therapies are projected to be eligible for negotiation in 2026 as well, including the kinase inhibitors Imbruvica (ibrutinib) and Ibrance (palbociclib) and the antiandrogen Xtandi (enzalutamide). In 2020, these 10 products accounted for $33.7 billion (17%) of Part D gross spending.

Based on their rank by gross spending, drugs likely to be negotiated for 2027 include 4 inhalers, 3 antidiabetics, 2 kinase inhibitors, the antipsychotic Invega Sustenna (paliperidone), the hepatitis C treatment Epclusa (sofosbuvir/velpatasvir), the irritable bowel syndrome therapy Linzess (linaclotide), the pancreatic enzyme mix Creon, the antibiotic Xifaxan (rixafimin), and the tardive dyskinesia therapy Ingrezza (valbenazine). The 15 products projected to be negotiated for 2027 accounted for $16.4 billion (8.3%) in gross Part D spending in 2020.

Case 3:23-cv-04818-JNQ Document 28-3 Filed 07/12/24 Page 287 of 423
Case: 24-1820 Document: 28-3 Page: 287 Date Filed: 07/12/2024 PageID: 423

TABLE 1 Drugs Anticipated to Face Medicare Price Negotiation, 2026-2028

Rank/part		Brand name	Generic name	Manufacturer	Spending in 2020[a], $	Years since approval[b]	Expected loss of exclusivity[c] (by year)	Minimum discount[d], %	CBO-estimated annual savings[e], $
Subject to negotiation in 2026									
1	D	Eliquis	Apixaban	BMS/Pfizer	9,936,069,814	13.0	2028	25	3.7 billion
2	D	Xarelto	Rivaroxaban	Janssen Pharm.	4,701,314,805	14.5	2027	25	
3	D	Januvia[f]	Sitagliptin phosphate	Merck Sharp & D	3,865,087,773	19.2	2026	60	
4	D	Imbruvica	Ibrutinib	Pharmacyclics	2,962,909,304	12.1	2033	25	
5	D	Jardiance	Empagliflozin	Boehringer Ing.	2,376,166,292	11.4	2028	25	
6	D	Enbrel	Etanercept	Amgen	2,154,714,778	27.2	2029	60	
7	D	Symbicort	Budesonide/formoterol	Astrazeneca	2,135,408,250	19.5	2028	60	
8	D	Ibrance	Palbociclib	Pfizer US Pharm	2,108,937,188	10.9	2034	25	
9	D	Xtandi	Enzalutamide	Astellas Pharma	1,968,567,948	13.4	2027	25	
10	D	Breo Ellipta	Fluticasone/vilanterol	Glaxosmithkline	1,504,155,910	12.7	2030	25	
Total 2026 drugs					**33,713,332,062**				
Subject to negotiation in 2027									
1	D	Trelegy Ellipta	Fluticasone/ umeclidinium/vilanterol	Glaxosmithkline	1,487,802,308	9.3	2027	25	8.3 billion (2027 savings from drugs negotiated in 2026-2027)
2	D	Ozempic	Semaglutide	Novo Nordisk	1,455,812,267	9.1	2031	25	
3	D	Invega Sustenna	Paliperidone palmitate	Janssen Pharm.	1,372,610,289	17.4	2031	60	
4	D	Jakafi	Ruxolitinib	Incyte Corporat	1,296,674,522	15.1	2028	25	
5	D	Tradjenta	Linagliptin	Boehringer Ing.	1,288,663,293	15.7	2027	25	
6	D	Ofev	Nintedanib esylate	Boehringer Ing.	1,157,563,828	12.2	2029	25	
7	D	Spiriva[g]	Tiotropium bromide	Boehringer Ing.	1,153,453,863	22.9	2030	60	
8	D	Linzess	Linaclotide	Allergan Inc.	1,144,468,128	14.4	2033	25	
9	D	Anoro Ellipta	Umeclidinium/vilanterol	Glaxosmithkline	1,002,343,776	13.1	2030	25	
10	D	Creon	Lipase/protease/amylase	Abbvie US LLC	960,235,542	17.8	2031	60	
11	D	Epclusa	Sofosbuvir/velpatasvir	Gilead Sciences	867,053,907	10.5	2034	25	
12	D	Xifaxan	Rifaximin	Salix Pharmaceu	844,562,189	22.6	2027	60	
13	D	Spiriva Respimat[g]	Tiotropium bromide	Boehringer Ing.	804,565,194	12.3	2030	25	
14	D	Ingrezza	Valbenazine tosylate	Neurocrine Bios	792,681,813	9.7	2038	25	
15	D	Janumet	Sitagliptin phos/ metformin hcl	Merck Sharp & D	791,886,114	19.7	2026	60	
Total 2027 drugs					**16,420,377,033**				

continued on next page

For 2028, Part B drugs will become eligible for negotiation. However, only 2 Part B products are projected to be subject to negotiation (Keytruda [pembrolizumab] and Opdivo [nivolumab]), as most high-spend Part B drugs will face biosimilar competition by then (Table 2). Given the 2 Part B products, 13 Part D products are projected to be subject to price negotiation for 2028, including 3 antidiabetics and 4 HIV treatments. The 15 products projected to be negotiated for 2028 accounted for $17.2 billion (8.7%) in gross Medicare spending in 2020. Combined, the 40

Case 3:23-cv-24180-TKW-HTC Document 28-3 Page 238 of 305 Filed 07/12/24 PageID: 424

TABLE 1 Drugs Anticipated to Face Medicare Price Negotiation, 2026-2028 *(continued)*

Rank/part		Brand name	Generic name	Manufacturer	Spending in 2020[a], $	Years since approval[b]	Expected loss of exclusivity[c] (by year)	Minimum discount[d], %	CBO-estimated annual savings[e], $
Subject to negotiation in 2028									
1	B	Keytruda	Pembrolizumab	Merck Sharp & D	3,500,947,569	13.3	2028	25	17.5 billion (2028 savings from drugs negotiated in 2026-2028)
2	D	Trulicity[h]	Dulaglutide	Eli Lilly & Co.	3,284,873,062	13.3	2027	25	
3	B	Opdivo	Nivolumab	BMS	1,586,591,103	13.0	2028	25	
4	D	Biktarvy	Bictegravir/ emtricitabine/tenofovir	Gilead Sciences	1,775,846,507	9.9	2036	25	
5	D	Genvoya	Elvitegravir/cobicistat/ emtricitabine/tenofovir	Gilead Sciences	755,819,244	12.2	2032	25	
6	D	Triumeq	Abacavir/dolutegravir/ lamivudine	Viiv Healthcare	738,986,222	13.4	2029	25	
7	D	Farxiga	Dapagliflozin	Astrazeneca	736,787,564	14.0	2030	25	
8	D	Tivicay	Dolutegravir	Viiv Healthcare	656,037,862	14.4	2029	25	
9	D	Lumigan[h]	Bimatoprost	Allergan Inc.	633,540,096	17.4	2027	60	
10	D	Acthar	Corticotropin	Mallinckrodt Ph	621,884,161	77.6	NA	60	
11	D	Incruse Ellipta	Umeclidinium	Glaxosmithkline	605,138,195	13.7	2030	25	
12	D	Pradaxa[h]	Dabigatran	Boehringer Ing.	599,577,175	17.2	2027	60	
13	D	Brilinta	Ticagrelor	Astrazeneca	588,513,924	16.5	2030	60	
14	D	Xeljanz XR	Tofacitinib citrate	Pfizer	575,315,148	11.9	2034	25	
15	D	Invokana	Canagliflozin	Janssen Pharm.	571,448,119	14.8	2031	25	
Total 2028 drugs					**17,231,305,951**				
Total 2026-2028 drugs					**67,365,015,046**				**29.5 billion**

[a]Estimates represent gross Part D spending in 2020 for Part D drugs and gross Part B spending in 2020 for Part B drugs. Spending estimates were obtained from the Medicare spending dashboards.

[b]Calculated as the time between drug approval and January 1 of the year that the drug is first expected to be subject to negotiation.

[c]Expected loss of exclusivity was estimated as the latest reported drug substance or drug product patent expiry date, superseded by any publicly announced patent settlement date.[17-19]

[d]Beginning in 2030, drugs from 12 to 15 years of age will be subject to a minimum 35% discount.

[e]Annual savings include ongoing savings from negotiated prices achieved in prior years.

[f]Although the entry of generic sitagliptin is expected in mid-2026, this will not disqualify Januvia from negotiation in 2026, as a generic product must have been marketed for at least 9 months prior to the implementation year for the reference product to be ineligible for negotiation.

[g]Spiriva and Spiriva Respimat were considered different products as they have different application numbers.

[h]Patent protection anticipated to expire after the first quarter of 2027, so any approved generics or biosimilars would not meet the 9-month marketing requirement prior to 2028.

BMS=Bristol Myers Squibb; CBO=Congressional Budget Office; NA=not applicable.

products projected to be eligible for negotiation for 2026-2028 accounted for $67.4 billion in gross Medicare spending in 2020, equivalent to 33.9%) of 2020 Part D spending or 28.4% of combined Part B and D drug spending.

We expect that 2028 will be the first year when a negotiated drug becomes ineligible for negotiated prices for the first time because generic competition, as Januvia and Janumet are expected to have generic competition launch in mid-2026. This launch timeline would not result in 9 months of a marketed generic prior to the start of 2027; therefore, we anticipate negotiated prices to remain in effect through the end of 2027.

In Table 2, we report high-spend products ineligible for negotiation because of statutory requirements. In all but 7 cases, drugs were disqualified because of generic or biosimilar competition. Products disqualified from negotiation

Case 3:24-cv-01820-JPG-DGW Document 28-3 Page 289 of 425 Date Filed: 07/12/2024
Case 3:24-cv-01820-JPG-DGW Document 30-5 Filed 08/16/24 Page 7 of 22 PageID: 425

TABLE 2 Top-Spending Drugs Ineligible for Medicare Price Negotiation, 2026-2028

Brand name	Generic name	Manufacturer	Spending in 2020[a], $	Reason ineligible
Part D drugs				
Revlimid	Lenalidomide	Celgene/BMS	5,356,050,275	Generic available
Humira	Adalimumab	Abbvie US LLC	4,166,710,387	Anticipated biosimilar in 2023
Lantus	Insulin glargine	Sanofi-Aventis	3,719,082,839	Biosimilar available
Novolog	Insulin aspart	Novo Nordisk	2,972,656,706	Interchangeable biosimilar anticipated by 2026
Humalog	Insulin lispro	Eli Lilly & Co.	2,064,366,203	Interchangeable biosimilar anticipated by 2026
Levemir Flextouch	Insulin detemir	Novo Nordisk	1,991,698,847	Interchangeable biosimilar anticipated by 2026
Victoza	Liraglutide	Novo Nordisk	1,895,291,574	Generic anticipated in 2023
Pomalyst	Pomalidomide	Celgene/BMS	1,453,860,767	Generic anticipated in 2026, and based on spending, it would not qualify until 2027
Restasis	Cyclosporine	Allergan Inc.	1,451,534,384	Generic available
Latuda	Lurasidone	Sunovion Pharma	1,317,919,887	Generic anticipated in 2023
Entresto	Sacubitril/valsartan	Novartis	1,203,043,540	Generic anticipated by 2025
Advair Diskus	Fluticasone/salmeterol	Glaxosmithkline	1,160,474,903	Generic available
Stelara	Ustekinumab	Janssen Biotech	1,106,356,248	Biosimilar anticipated in 2024
Tecfidera	Dimethyl fumarate	Biogen-Idec	1,054,984,601	Generic available
Shingrix	Varicella-zoster	Glaxosmithkline	875,670,149	Ineligible based on years since approval
Janumet	Sitagliptin/metformin	Merck Sharp & D	791,886,114	Generic anticipated in 2026, and based on spending, it would not qualify until 2027
Aubagio	Teriflunomide	Sanofi-Aventis	778,201,329	Generic anticipated in 2023
Vascepa	Icosapent ethyl	Amarin Pharma	754,811,701	Generic available
Copaxone	Glatiramer acetate	Teva Neuroscien	713,588,637	Generic available
Vimpat	Lacosamide	UCB Pharma	709,365,915	Generic available
Basaglar	Insulin glargine	Eli Lilly & Co.	689,339,162	Ineligible based on years since approval
Dexilant	Dexlansoprazole	Takeda	651,674,922	Generic available
Part B drugs				
Eylea	Aflibercept	Regeneron	3,013,081,886	Biosimilar anticipated in 2024
Prolia	Denosumab	Amgen	1,626,844,123	Biosimilar anticipated in 2025
Rituxan	Rituximab	Roche	1,295,821,133	Biosimilar available
Lucentis	Ranibizumab	Genentech	1,113,026,180	Biosimilar available
Orencia	Abatacept	BMS	1,023,001,524	Biosimilar anticipated in 2026
Neulasta	Pegfilgrastim	Amgen	899,790,555	Biosimilar available
Darzalex	Daratumumab	Johnson & Johnson	837,400,702	Not eligible until 2029 because of years since approval
Avastin	Bevacizumab	Genentech	680,539,026	Biosimilar available
Remicade	Infliximab	Janssen	663,412,142	Biosimilar available
Tecentriq	Atezolizumab	Genentech	624,194,084	Not eligible until 2030 because of years since approval
Ocrevus	Ocrelizumab	Genentech	618,708,736	Not eligible until 2031 because of years since approval
Soliris	Eculizumab	Alexion	610,425,468	Biosimilar anticipated in 2025

[a]Estimates represent gross Part D spending in 2020 for Part D drugs and gross Part B spending in 2020 for Part B drugs. Spending estimates were obtained from the Medicare spending dashboards.[5,10]

BMS=Bristol Myers Squibb.

Case 3:23-cv-04820-TLT-DMR Document 28-3 Page 290 of 308 Filed 07/12/24 Page ID: 426

include insulin products, which are expected to face competition from biosimilars by 2026, and the blockbuster Humira (adalimumab), which is expected to face biosimilar competition in 2023.

Discussion

To our knowledge, our article is the first public report of the drugs anticipated to be negotiated by CMS for benefit years 2026-2028. Our estimates differ from an earlier list of negotiation-eligible drugs for 2026 that did not consider LOE after 2022, as acknowledged by the authors.[11] With the exception of 2 insulin products, which we believe will face biosimilar competition by 2026, our list is consistent with a previous report of expected drugs to be negotiated in 2026 that did account for LOE.[12] We have excluded NovoLog (insulin aspart) from the list of drugs eligible for negotiation as patents have expired and the FDA is currently reviewing a biosimilar application.[13] We have considered Levemir (insulin detemir) ineligible for negotiation because the manufacturer reports that US patents expired in June 2019,[14] thus meeting our study exclusion criteria even though no biosimilar is yet available. Additionally, although the generic formulation of Revlimid (lenalidomide) is currently subject to volume limitations until January 2026,[15] this generic is considered "marketed" under FDA criteria, thereby excluding Revlimid from negotiation eligibility.

Some Medicare patients will benefit substantially from negotiations on these drugs, as a reduction in the drug's price will result in lower coinsurance and liability during the deductible phase. Overall, negotiations are projected by the CBO to reduce premiums, resulting in lower costs for all Medicare beneficiaries.[4,16] Notably, the minimum price reductions listed almost certainly underrepresent the price reductions that will be achieved for the Part D drugs, as the negotiated price is required to be below the existing average net price of the drug, which includes confidential rebates. Thus, Medicare patients may see their cost sharing fall by amounts greater than reflected by the minimum price reductions reported, as their cost sharing will reflect, at minimum, existing net prices.

Overall, Medicare negotiation will benefit patients on the specific medications identified across some of the most common disease areas while reducing total Medicare drug spending. The Inflation Reduction Act coupled CMS negotiation with substantial reforms to the Medicare Part D benefit design, most notably a $2,000 out-of-pocket cap. Absent CMS negotiation, these benefit changes are estimated to increase Medicare spending by $30 billion, but the savings generated through CMS negotiation offset these increases.[4]

LIMITATIONS

Our findings are subject to 2 main limitations. First, our selection of top-spending drugs is based on data from 2020, the most recent available at the time of analysis. Changes in drug utilization and pricing over time may affect which drugs are ultimately selected for negotiation based on total spending in the year prior to negotiation. Second, our list of drugs eligible for negotiation is subject to the uncertain outcomes of ongoing patent litigation, which could affect the date of predicted generic or biosimilar entry.

Conclusions

We estimate that Medicare will negotiate 38 Part D and 2 Part B drugs in 2026-2028, including 7 inhalers, 8 antidiabetics, 5 kinase inhibitors, and 3 oral anticoagulants. Combined, the 40 products eligible for negotiation in 2026-2028 accounted for $67.4 billion in gross Medicare spending in 2020. By identifying a list of drugs likely to be negotiated by CMS, we hope to provide researchers, policymakers, prescribers, and patient advocates with expectations on which drugs will see reductions in beneficiary cost sharing.

DISCLOSURES

This work was funded by the West Health Policy Center. Dr Hernandez reports consulting fees from Pfizer and Bristol Myers Squibb, outside of the submitted work.

REFERENCES

1. Inflation Reduction Act of 2022. HR 5376, 117th Cong (2022). Accessed January 19, 2023. https://www.congress.gov/bill/117th-congress/house-bill/5376/text

2. Center for Drug Evaluation and Research. Marketing status notifications under section 506I of the Federal Food, Drug, and Cosmetic Act. US Food and Drug Administration. Accessed January 24, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-status-notifications-under-section-506i-federal-food-drug-and-cosmetic-act

3. Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program: Next steps in implementation for initial price applicability year 2026. Published January 11, 2023. Accessed January 19, 2023. https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf

4. Congressional Budget Office. Estimated budgetary effects of Public Law 117-169, to provide for reconciliation pursuant to Title II of S. Con. Res. 14. Published 2022. Accessed September 29, 2022. https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf

Case 3:23-cv-04818-ZNQ-DEA Document 28-3 Filed 08/16/23 Page 29 of 32 PageID: 427
Case: 24-1820 Document: 28-3 Page: 291 Date Filed: 07/12/2024

5. Medicare Part D spending dashboard. Centers for Medicare & Medicaid Services. Accessed September 29, 2022. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug

6. Medicare Part B spending dashboard. Centers for Medicare & Medicaid Services. Accessed January 19, 2023. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug

7. Drugs@FDA database. US Food and Drug Administration. Accessed January 19, 2023. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

8. Center for Drug Evaluation and Research. Approved drug products with therapeutic equivalence evaluations|Orange Book. US Food and Drug Administration. Accessed September 14, 2022. https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book

9. Cardinal Health. 2022 Biosimilars Report: The US journey and path ahead. Accessed September 9, 2022. https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-2022-biosimilars-report.pdf

10. Medicaid spending dashboard. Centers for Medicare & Medicaid Services. Accessed January 19, 2023. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicaid-spending-by-drug

11. Hwang TJ, Kesselheim AS, Rome BN. New reforms to prescription drug pricing in the US: Opportunities and challenges. JAMA. 2022;328(11):1041-2. doi:10.1001/jama.2022.15268

12. Johnson M, Nayak R, Kishore S. Which drug prices will Medicare negotiate first? A physicians' perspective. *Health Affairs Forefront*. September 30, 2022. doi:10.1377/forefront.20220929.242021

13. Hagen T. Investigators report high similarity between NovoLog and biosimilar candidate. Managed Healthcare Executive. Published October 20, 2022. Accessed January 24, 2023. https://www.managedhealthcareexecutive.com/view/investigators-report-high-similarity-between-novolog-and-biosimilar-candidate

14. Novo Nordisk. Annual Report to the US Securities and Exchange Commission: Form 20-F. Accessed January 19, 2023. https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2020/Novo-Nordisk-Form-20-f-2019.pdf

15. Celgene settles US REVLIMID® patent litigation with Alvogen. Celegene. Accessed January 24, 2023. https://ir.celgene.com/press-releases-archive/press-release-details/2019/Celgene-Settles-US-REVLIMID-Patent-Litigation-with-Alvogen/default.aspx

16. CBO estimates drug savings for reconciliation. Committee for a responsible federal budget. Accessed January 25, 2023. https://www.crfb.org/blogs/cbo-estimates-drug-savings-reconciliation

17. US Securities and Exchange Commission. Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31,2021. Form 10-K. Bristol-Myers Squibb Company. Accessed September 29, 2022. https://d18rn0p25nwr6d.cloudfront.net/CIK-0000014272/f4a6942f-7e0d-4d3e-9ef4-b3b0a9d617d7.pdf

18. US District Court rules in favor of Merck in sitagliptin phosphate patent lawsuit. Merck. Published September 22, 2022. Accessed September 29, 2022. https://www.merck.com/news/u-s-district-court-rules-in-favor-of-merck-in-sitagliptin-phosphate-patent-lawsuit/

19. De Backer M, Rommel C, Olerich S. Transforming pharma to deliver sustainable longterm growth. Bayer Capital Markets Day. Published March 10, 2021. Accessed September 29, 2022. https://www.bayer.com/sites/default/files/BayerCMD2021_Pharma_Presentation_0.pdf

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Exhibit D

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Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)

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Contents

Tables

Table 1. Subtitle A—Deficit Reduction 2
Table 2. Subtitle B—Prescription Drug Reform 4
Table 3. Subtitle C—Affordable Care Act Subsidies 5
Table 4. Subtitle D—Energy Security 5
Table 5. Estimated Budgetary Effect of the Revenue Provisions of the "Inflation Reduction Act of 2022" 24

Table A-1. Subtitle A—Deficit Reduction 28
Table A-2. Subtitle B—Prescription Drug Reform 29
Table A-3. Estimated Budgetary Effect of the Revenue Provisions of the "Inflation Reduction Act of 2022" 31

Appendixes

Appendix. Inflation Reduction Act as Initially Proposed in the Senate 28

Contacts

Author Information 35

On July 27, 2022, Senate Majority Leader Chuck Schumer and Senator Joe Manchin released legislative text for budget reconciliation legislation, also known as the "Inflation Reduction Act of 2022."[1] On August 7, 2022, the Senate passed a modified version of the Inflation Reduction Act of 2022.[2] This text will replace the legislative text of the House-passed Build Back Better Act (BBBA; H.R. 5376) as a substitute amendment.[3]

This report summarizes the tax provisions in the Inflation Reduction Act of 2022, which include

- establishing a corporate minimum tax;
- imposing an excise tax on corporate stock repurchases;
- establishing an excise tax on drug manufacturers, producers, and importers who fail to enter into drug pricing agreements;
- extending the health insurance premium tax credit modifications made in the American Rescue Plan Act of 2021 (ARPA; P.L. 117-2) through 2025; and
- modifications to the tax treatment of the energy sector that would generally reduce revenues; including
  - extension and modification of the credit for electricity produced from certain renewable resources;
  - extension and modification of the energy credit; and
  - extension of excise tax credits for alternative fuels, biodiesel, and renewable diesel.

All tax provisions in the Inflation Reduction Act of 2022 text are summarized in a series of tables below. References to relevant CRS reports are included where applicable.

- **Table 1** includes the provisions in Subtitle A, Deficit Reduction;
- **Table 2** includes the provisions in Subtitle B, Prescription Drug Pricing Reform;
- **Table 3** includes the provisions in Subtitle C, Affordable Care Act Subsidies; and
- **Table 4** includes the provisions in Subtitle D, Energy Security.

Provisions in Subtitle A, as passed on August 7, 2022, were modified from what was introduced on July 27. Specifically, the July 27 version included changes to the tax treatment of carried interest. This provision was not included in the Senate-passed version. The Senate-passed version instead included an excise tax on corporate stock repurchases and an extension of loss limits for pass-through businesses. Additionally, the Senate-passed version made some modifications to the corporate minimum tax. **Table 1** includes information on the provisions in the Senate-passed version of the IRA, while **Table A-1** includes the provisions that were in Subtitle A in the July 27

[1] Legislative text for the Inflation Reduction Act of 2022 is available at https://www.democrats.senate.gov/inflation-reduction-act-of-2022.

[2] The text as passed by the Senate on August 7, 2022, can be found on the House Rules Committee website at https://rules house.gov/bill/117/hr-5376-sa. The updated text for the Inflation Reduction Act of 2022 was originally introduced in the Senate as an amendment in the nature of a substitute (S.Amdt. 5194). Two other amendments were agreed to during Senate consideration (S.Amdt. 5472 and S.Amdt. 5488). The text of these amendments can be found at https://ats.senate gov/Index.aspx?view=11010001&type=2&bill=H.R.5376.

[3] For information on the provisions in the Build Back Better Act, see CRS Report R46998, *Senate Finance Committee Tax Provisions in the Build Back Better Act*, coordinated by Molly F. Sherlock; CRS Report R46960, *Tax Provisions in the Build Back Better Act: Rules Committee Print 117-18*, coordinated by Molly F. Sherlock; and CRS Report R46923, *Tax Provisions in the "Build Back Better Act:" The House Ways and Means Committee's Legislative Recommendations*, coordinated by Molly F. Sherlock.

version of the IRA. **Table A-2** also includes the provisions that were in subtitle B in the July 27 version of the IRA that were modified in the Senate-passed version. **Table 4** also includes the provisions that were newly added as the IRA was being considered in the Senate.

The Joint Committee on Taxation (JCT) has estimated that the Senate-passed version of the IRA would increase federal tax revenue by $90.7 billion over the 10-year FY2022 through FY2031 budget window.[4] The revenue provisions in Subtitle A would generate additional federal tax revenue of an estimated $295.9 billion over this period. The mostly energy-related provisions in Subtitle D would reduce federal tax revenue by an estimated $205.2 billion over the 10-year period (additional non-energy-related revenues of $53.8 billion would come from extending the limits on excess business losses for noncorporate taxpayers by two years, after 2026). The JCT revenue estimate is presented in **Table 5**. JCT's preliminary revenue estimate of the IRA before Senate consideration can be found in **Table A-3**.

Table 1. Subtitle A—Deficit Reduction

Section Title	Description	CRS Resources
Part 1—Corporate Tax Reform		
Corporate Alternative Minimum Tax Section 10101	This provision would impose a new alternative minimum tax of 15% on corporations based on financial income. It would apply to corporations with $1 billion or more in average annual earnings in the previous three years. In the case of U.S. corporations that have foreign parents, it would apply only to income earned in the United States of $100 million or more of average annual earnings in the previous three years (and apply when the international financial reporting group has income of $1 billion or more). It would apply to a new corporation in existence for less than three years based on the earnings in the years of existence. The provision would exclude Subchapter S corporations, regulated investment companies (RICs), and real estate investment trusts (REITs). The tax would apply would to large private equity firms organized as partnerships, but excludes portfolio companies owned by these firms (due to a modification made by Section 13904 of the bill). Firms that file consolidated returns would include income allocable to the firm from related firms including controlled foreign corporations (and any disregarded entities); for other related firms, dividends would be included. The provision would allow special deductions for cooperatives and Alaska Native Corporations. It would make adjustments to conform financial accounting to tax accounting for certain defined benefit pension plans. It would apply with respect to items under the unrelated business income tax for tax-exempt entities. Financial income would be adjusted to allow depreciation deductions based on tax rules. It would also be adjusted to	For background, see • CRS In Focus IF12179, *The Corporate Minimum Tax Proposal*, by Jane G. Gravelle. • CRS Report R46887, *Minimum Taxes on Business Income: Background and Policy Options*, by Molly F. Sherlock and Jane G. Gravelle. • CRS Insight IN11646, *A Look at Book-Tax Differences for Large Corporations Using Aggregate Internal Revenue Service (IRS) Data*, by Molly F. Sherlock and Jane G. Gravelle.

[4] Joint Committee on Taxation, *Estimated Budgetary Effect of the Revenue Provisions of Title I -Committee on Finance, of an Amendment in the Nature of a Substitute to H.R. 5376, "An Act to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14," as Passed by the Senate on August 7, 2022, and Scheduled for Consideration by the House of Representatives on August 12, 2022,"* JCX-18-22, August 9, 2022, https://www.jct.gov/publications/2022/jcx-18-22/.

Section Title	Description	CRS Resources
	allow recovery of wireless spectrum rights as allowed under tax rules (recovered over 15 years). The additional tax would equal the amount of the minimum tax in excess of the regular income tax plus the additional tax from the Base Erosion and Anti-Abuse tax. Income would be increased by federal and foreign income taxes to place income on a pretax basis. Losses would be allowed in the same manner as with the regular tax, with loss carryovers limited to 80% of taxable income. Domestic credits under the general business tax (such as the R&D credit) would be allowed to offset up to 75% of the combined regular and minimum tax. Foreign tax credits would be allowed based on the allowance for foreign taxes paid in a corporation's financial statement. A credit for additional minimum tax could be carried over to future years to offset regular tax when that tax is higher. This tax would apply to taxable years beginning after December 31, 2022.	
Part 2—Excise Tax on Repurchase of Corporate Stock		
Excise Tax on Repurchase of Corporate Stock Section 10201	This provision would impose a 1% excise tax on the repurchase of stock by a publicly traded corporation. The amount subject to tax would be reduced by any new issues to the public or stock issued to employees. The tax would not apply if repurchases are less than $1 million or are contributed to an employee pension or similar plan. The tax would not apply if the repurchases are treated as a dividend. It also would not apply to repurchases by regulated investment companies (RICs) or real estate investment trusts (REITs). Further, it would not apply to repurchases that are treated as dividends or to purchases by a dealer in securities in the ordinary course of business. The excise tax would apply to purchases of corporation stock by a subsidiary of the corporation (a corporation or partnership that is more than 50% owned). The tax would also apply to purchases by a U.S. subsidiary of a foreign-parented firm. It would apply to newly inverted (after September 20, 2021) or surrogate firms (firms that merged to create a foreign parent with the former U.S. shareholders owning more than 60% of shares). The tax would not be deductible. The tax would apply to repurchases after December 31, 2022.	For background, see • CRS In Focus IF11960, *An Excise Tax on Stock Repurchases and Tax Advantages of Buybacks over Dividends*, by Jane G. Gravelle. • CRS Legal Sidebar LSB10266, *Stock Buybacks: Background and Reform Proposals*, by Jay B. Sykes. • CRS In Focus IF11393, *Stock Buybacks: Concerns over Debt-Financing and Long-Term Investing*, by Gary Shorter. • CRS In Focus IF11506, *Stock Buybacks and Company Executives' Profits*, by Gary Shorter.

Source: CRS analysis of the legislative text of the Senate amendment to H.R. 5376, "Inflation Reduction Act of 2022," as posted on the House Rule Committee Website at https://rules.house.gov/bill/117/hr-5376-sa.

Notes: The changes that would be made by these provisions are permanent. Part 3 of Subtitle A would provide additional appropriations of $79.6 billion over the next 10 years to enhance IRS service and enforcement activities. For background on IRS appropriations, see CRS Insight IN11977, *IRS-Related Funding in the Inflation Reduction Act*, by Brendan McDermott; and CRS In Focus IF12098, *Internal Revenue Service Appropriations, FY2023*, by Gary Guenther.

Table 2. Subtitle B—Prescription Drug Reform

Section Title	Description	CRS Resources
Part I—Lowering Prices Through Drug Price Negotiations		
Selected Drug Manufacturer Excise Tax Imposed During Noncompliance Period Section 11003	This provision would impose a new excise tax on drug manufacturers, producers, and importers who fail to enter into drug pricing agreements under Section 1193 of the Social Security Act, as added by the bill on selected drugs (i.e., are noncompliant with Section 1193). This excise tax would be found under the new Internal Revenue Code (IRC) Section 5000D. The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance. The provision does not specify these rates explicitly, but instead defines an applicable percentage which equals the share of the post-tax sale price attributable to the excise tax. Specifically, the applicable percentage as defined in the statute equals tax/(tax+price) which simplifies to tax rate/(tax rate+1) with the applicable percentages being 65% for the sales of selected drugs during the first 90 days of noncompliance, 75% for sales during the 91st to 180th days of noncompliance, 85% for sales during the 181st to 270th days of noncompliance, and 95% for sales after the 270th day of noncompliance. Hence, the corresponding tax rates would be calculated as (applicable percentage)/(1-applicable percentage) and equal 185.71%, 300%, 566.67% and 1,900% respectively, depending on the duration of noncompliance. For example, if a selected drug was subject to the top tax rate of 1,900% and cost $10 pre-tax, it would cost $200 post-tax with $190 of the $200 cost (or 95%, the applicable percentage) being attributable to the excise tax. Selected drugs would be those defined in Section 1192(a) of the Social Security Act, as enacted under this bill, which are manufactured or produced in the United States or enter into the United States for consumption, use, or warehousing. The excise tax would not apply to drugs sold for export, and the provision addresses the refund or credit process if tax is paid. Noncompliance periods as defined in the bill would generally begin after the deadline to enter into an agreement to negotiate or renegotiate, or to agree upon a maximum price, had passed. Such periods would end when such agreement has been reached. The noncompliance period would also end if a generic version of the selected drug becomes available. The earliest potential noncompliance period would begin on October 2, 2023. The excise tax would be suspended during any period in which none of the drugs made by a selected drug's manufacturer are covered by a Medicaid Drug Rebate Program agreement, a Medicare Part D Coverage Gap Discount agreement, or a Medicare Part D Manufacturer Discount Program agreement.	For background, see • CRS Report R47056, *Build Back Better Act (BBBA) Health Coverage Provisions: House-Passed and Senate-Released Language*, coordinated by Vanessa C. Forsberg and Ryan J. Rosso.

Section Title	Description	CRS Resources
	For sales that were timed to avoid the excise tax, the Secretary of the Treasury could treat the sale as occurring during a day in a noncompliance period. Manufacturers would be prohibited from deducting excise tax payments from their federal income taxes.	

Source: CRS analysis of the legislative text of the Senate amendment to H.R. 5376, "Inflation Reduction Act of 2022," as posted on the House Rule Committee Website at https://rules.house.gov/bill/117/hr-5376-sa.

Notes: This provision would apply after the date of enactment to the sale of drugs during a noncompliance period. The first noncompliance period could begin on October 2, 2023. Within the description, "Section" citations refer to the section within the Internal Revenue Code (IRC), 26 U.S.C., unless otherwise noted.

Table 3. Subtitle C—Affordable Care Act Subsidies

Section Title	Description	CRS Resources
Improve Affordability and Reduce Costs of Health Insurance for Consumers Section 12001	Under current law, income eligibility for and calculation of the premium tax credit (PTC) incorporates temporary changes enacted under the American Rescue Plan Act of 2021 (ARPA; P.L. 117-2). For 2021 and 2022, ARPA expanded income eligibility by eliminating the phaseout for households with annual incomes above 400% of the federal poverty level (FPL). For those same years, ARPA also increased credit amounts by adjusting the percentage of annual income that eligible households may be required to contribute toward the premium. The percentages currently range from 0.0% to 8.5% of household income, with higher-income groups subject to larger percentages, as specified. This provision would extend these ARPA changes to 2023, 2024, and 2025.	For background, see • CRS Report R44425, *Health Insurance Premium Tax Credit and Cost-Sharing Reductions*, by Bernadette Fernandez.

Source: CRS analysis of the legislative text of the Senate amendment to H.R. 5376, "Inflation Reduction Act of 2022," as posted on the House Rule Committee Website at https://rules.house.gov/bill/117/hr-5376-sa.

Notes: The provision in this table is effective for taxable years beginning after December 31, 2022.

Table 4. Subtitle D—Energy Security

Section Title	Description	CRS Resources
Part 1—Clean Electricity and Reducing Carbon Emissions		
Extension and Modification of Credit for Electricity Produced from Certain Renewable Resources Section 13101	Current law provides a production tax credit (PTC), at a rate of 2.5 cents or 1.3 cents per kilowatt hour (kWh) depending on the technology used, for the first 10 years of production at qualifying renewable electricity production facilities that began construction before 2022. The credit amount is adjusted annually for inflation from a statutory rate of 1.5 cents per kWh, with some technologies qualifying for a half-credit amount. This provision would extend the PTC for wind, biomass, geothermal, solar (which previously expired at the end of 2005), landfill gas, trash, qualified hydropower, and marine and hydrokinetic resources through 2024. The base credit amount for the PTC would be set in statute at 0.3 cents per kWh (0.5 cents per kWh in 2021, or 0.3 cents for half-credit technologies, after being adjusted for inflation). Facilities that pay prevailing wages during the construction phase and first 10 years of	For background, see • CRS Report R43453, *The Renewable Electricity Production Tax Credit: In Brief*, by Molly F. Sherlock. • CRS Report R46865, *Energy Tax Provisions: Overview and Budgetary Cost*, by Molly F. Sherlock. • CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F.

Section Title	Description	CRS Resources
	operation and meet registered apprenticeship requirements are eligible for a PTC that is five times the base amount, or 2.5 cents or 1.3 cents per kWh in 2021 after being adjusted for inflation. Facilities with a maximum net output of less than one megawatt are also eligible for the five times base credit amount (e.g., 2021 rates of 2.5 cents or 1.3 cents per kWh), as are facilities that begin construction before 60 days after the Secretary of the Treasury publishes guidance on the wage and registered apprenticeship requirements. Qualifying hydropower and marine and hydrokinetic renewable energy projects, which are half-credit technologies under current law, would be allowed the full PTC. A "bonus credit" amount would be provided for projects that meet domestic content requirements to certify that certain steel, iron, and manufactured products used in the facility were domestically produced. The bonus credit amount would be 10% of the credit amount. In 2024, the amount of the credit that could be received as direct pay would be limited to 90% for large facilities not meeting domestic content requirements (see "Elective Payment for Energy Property and Electricity Produced from Certain Renewable Resources, Etc." below). This limit would be waived if materials are not available domestically or if including domestic materials would increase the facility's construction cost by more than 25%. The credit amount could be increased by 10% for facilities located in an energy community. An energy community is defined as being a brownfield site; an area which has or had certain amounts of direct employment or local tax revenue related to oil, gas, or coal activities and has an unemployment rate at or above the national average; or a census tract or any adjoining tract in which a coal mine closed after December 31, 1999, or in which a coal-fired electric power plant was retired after December 31, 2009. The provision provides that for facilities financed with tax-exempt bonds, the credit amount would be reduced by the lesser of (1) 15%; or (2) the fraction of the proceeds of a tax-exempt obligation used to finance the project over the aggregate amount of the project's financing costs. The proposal also extends the option to claim the energy investment tax credit (ITC) in lieu of the PTC.	Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples. • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro. • CRS Insight IN11983, *Proposed Tax Preference for Domestic Content in Energy Infrastructure*, by Christopher D. Watson and Molly F. Sherlock.
Extension and Modification of Energy Credit Section 13102	Current law provides a temporary investment tax credit (ITC) for investments in certain energy property. This provision would extend and modify the ITC, with the credit generally extended through the end of 2024. The ITC would be extended through 2024 at a base rate of 6% for solar, fuel cells, waste energy recovery, combined heat and power, and small wind property, and 2% for microturbine property. These amounts would be increased to 30% and 10%, respectively, if projects pay prevailing wages during the construction phase and during the first five years of operation and meet registered apprenticeship requirements. The higher credit rates	For background, see • CRS In Focus IF10479, *The Energy Credit or Energy Investment Tax Credit (ITC)*, by Molly F. Sherlock. • CRS Report R46865, *Energy Tax Provisions: Overview and Budgetary Cost*, by Molly F. Sherlock.

Section Title	Description	CRS Resources
	would also be available to any project with a maximum net output of less than one megawatt of electrical or thermal energy and for facilities that begin construction before 60 days after the Secretary of the Treasury publishes guidance on the wage and registered apprenticeship requirements. The ITC for geothermal heat pumps would be extended through 2034 with a 6% base credit rate with the 30% credit rate allowed for projects meeting wage and workforce requirements or for projects below the maximum net output threshold. The credit would phase down after 2032, with the rates being 5.2% and 26% in 2033 and 4.4% and 22% in 2034, with no credit allowed for property beginning construction after 2035. This list of qualifying property would be expanded to include energy storage technology (including thermal energy storage property), qualified biogas property, electrochromic glass, and microgrid controllers at the 6% or 30% rate. Linear generator assemblies would be added to the definition of qualifying fuel cells. The credit would also be available for interconnection property. Public utilities, under certain circumstances, would be able to elect out of normalization requirements for investments in energy storage technologies. A "bonus credit" amount would be provided for projects that meet domestic content requirements to certify that certain steel, iron, and manufactured products used in the facility were domestically produced. The bonus credit amount would be 2 percentage points, or 10 percentage points for projects that meet wage and workforce requirements. In 2024, the amount of the credit that could be received as direct pay would be limited to 90% for large facilities not meeting domestic content requirements (discussed below). This limit would be waived if materials are not available domestically or if including domestic materials would increase the facility's construction cost by more than 25%. The provision provides that for facilities financed with tax-exempt bonds, the credit amount would be reduced by the lesser of (1) 15%; or (2) the fraction of the proceeds of a tax-exempt obligation used to finance the project over the aggregate amount of the project's financing costs. An increased credit amount would be available to projects in an energy community, with the credit increase being 10 percentage points for projects meeting wage and workforce requirements or 2 percentage points otherwise. An energy community is defined as being a brownfield site; an area which has or had certain amounts of direct employment or local tax revenue related to oil, gas, or coal activities and has an unemployment rate at or above the national average; or a census tract or any adjoining tract in which a coal mine closed after December 31, 1999, or in which a coal-fired electric power plant was retired after December 31, 2009.	• CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples. • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro. • CRS Insight IN11983, *Proposed Tax Preference for Domestic Content in Energy Infrastructure*, by Christopher D. Watson and Molly F. Sherlock.

Section Title	Description	CRS Resources
Increase in Energy Credit for Solar and Wind Facilities Placed in Service in Connection with Low-Income Communities Section 13103	This provision would allow for the allocation of 1.8 gigawatts for "environmental justice solar and wind capacity" credits in each of calendar year 2023 and 2024. Taxpayers receiving a capacity allocation may be entitled to tax credits in addition to otherwise allowed ITCs. Specifically, projects receiving an allocation that are located in a low-income community or on Indian land would be eligible for a bonus investment tax credit of 10 percentage points, while projects that are part of a low-income residential building project or qualified low-income economic benefit project would be eligible for a 20 percentage point bonus investment credit. Qualifying solar and wind facilities would include those with a nameplate capacity of 5 megawatts or less, and qualifying property would include energy storage property installed in connection with the solar property and interconnection property. Facilities receiving an allocation would be required to have the facility placed in service within four years.	For background on the ITC, see • CRS In Focus IF10479, *The Energy Credit or Energy Investment Tax Credit (ITC)*, by Molly F. Sherlock. For background on housing assistance programs, see • CRS Report RL34591, *Overview of Federal Housing Assistance Programs and Policy*, by Maggie McCarty, Libby Perl, and Katie Jones.
Extension and Modification of Credit for Carbon Oxide Sequestration Section 13104	Under current law, industrial carbon capture or direct air capture (DAC) facilities that begin construction by December 31, 2025, can qualify for the Section 45Q tax credit for carbon oxide sequestration. This tax credit can be claimed for carbon oxide captured during the 12-year period following a qualifying facility's being placed in service. Currently, the per metric ton tax credit for geologically sequestered carbon oxide is set to increase to $50 per ton by 2026 ($35 per ton for carbon oxide that is reused, such as for enhanced oil recovery) and adjusted for inflation thereafter. This provision would extend the start of construction deadline to December 31, 2032. The amount of carbon oxide that must be captured at a qualifying facility would be reduced to 1,000 metric tons annually for a DAC facility, 18,750 metric tons annually for an electricity generating facility (and be designed to capture not less than 75% of the baseline carbon oxide production), and 12,500 metric tons for any other facility. Base credit amounts would be $17 per metric ton for carbon oxide that is captured and geologically sequestered and $12 per metric ton for carbon oxide that is reused. Increased credit amounts of $85 per ton and $60 per ton, respectively, would be available for facilities that pay prevailing wages during the construction phase and during the first 12 years of operation and meet registered apprenticeship requirements. The credit amount for carbon oxide captured using DAC and geologically sequestered would be increased to a base rate of $36 per metric ton, with a credit of $180 per metric ton for projects that meet wage and workforce requirements. These amounts would be $26 and $130 per metric ton for carbon oxide captured using DAC that is utilized in a qualified manner. Projects financed with tax-exempt bonds would have the credit amount reduced by the lesser of (1) 15%; or (2) the fraction of the proceeds of a tax-exempt obligation used	For background, see • CRS In Focus IF11455, *The Tax Credit for Carbon Sequestration (Section 45Q)*, by Angela C. Jones and Molly F. Sherlock. • CRS Insight IN11710, *Carbon Capture and Sequestration Tax Credit ("Section 45Q") Legislation in the 117th Congress*, by Molly F. Sherlock and Angela C. Jones. • CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples. • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.

Section Title	Description	CRS Resources
	to finance the project over the aggregate amount of the project's financing costs. The provision would also provide flexibility with respect to the period in which credits can be claimed for projects affected by federally declared disasters.	
Zero-Emission Nuclear Power Production Credit Section 13105	This provision would create a new tax credit for qualifying zero-emission nuclear power produced and sold after December 31, 2023. Qualified nuclear power facilities are taxpayer-owned facilities that use nuclear power to generate electricity that did not receive an advanced nuclear production tax credit allocation under Section 45J, and are placed in service before the date of enactment (i.e., are existing nuclear power plants). The PTC amount would be 0.3 cents per kWh. The credit would be reduced when the price of electricity increases. Credits would be reduced by a "reduction amount," which is 16% of the excess of gross receipts from electricity produced by the facility and sold over the product of 2.5 cents times the amount of electricity sold during the taxable year. Thus, the credit would phase down as annual average prices exceed 2.5 cents per kWh. Taxpayers that satisfy prevailing wage and registered apprenticeship requirements would be eligible for a tax credit of five times the base amount per kWh (i.e., up to 1.5 cents per kWh). Credit amounts and amounts in the reduction amount formula would be adjusted for inflation. The credit would terminate on December 31, 2032.	For background, see • CRS Report R42853, *Nuclear Energy: Overview of Congressional Issues*, by Mark Holt. • CRS Insight IN10725, *The Advanced Nuclear Production Tax Credit*, by Molly F. Sherlock and Mark Holt. • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.
Part 2—Clean Fuels		
Extension of Incentives for Biodiesel, Renewable Diesel, and Alternative Fuels Section 13201	Current law provides a 50-cents-per-gallon tax credit for alternative fuels and alternative fuel mixtures through 2021 and a $1.00-per-gallon tax credit for biodiesel and renewable diesel (with an additional $0.10-per-gallon tax credit for agri-biodiesel) through 2022. The biodiesel and renewable diesel mixtures tax credit may be claimed as an immediate excise tax credit against the blender's motor and aviation fuels excise taxes. Credits in excess of excise tax liability may be refunded. The biodiesel and small agri-biodiesel credits may be claimed as income tax credits. The alternative fuels credit can be claimed as an excise tax credit or received as an outlay. The alternative fuels mixture credit is an excise tax credit. This provision would extend the existing tax credits for alternative fuels and alternative fuel mixtures and biodiesel and renewable diesel through December 31, 2024. This provision would establish a special rule for paying claims for tax credits during the period of retroactive eligibility. The biodiesel and renewable diesel credit, alternative fuel credit, alternative fuel mixture credit, and payments for alternative fuels expired at the end of 2021. This provision would allow those credits for all of 2022. The IRS would need to create a process within 30 days of enactment for one-time claims for these tax credits. Taxpayers would have 180 days to submit a claim, which	For background, see • CRS Report R46865, *Energy Tax Provisions: Overview and Budgetary Cost*, by Molly F. Sherlock. • CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples.

Section Title	Description	CRS Resources
	would need to be paid within 60 days of receipt (interest would be paid on any payment made after that date).	
Extension of Second Generation Biofuel Incentives Section 13202	Current law provides a $1.01-per-gallon income tax credit for second-generation biofuel production through 2021. This provision would extend the second-generation biofuel producer tax credit through December 31, 2024.	For background, see • CRS Report R46865, *Energy Tax Provisions: Overview and Budgetary Cost*, by Molly F. Sherlock. • CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples.
Sustainable Aviation Fuel Credit Section 13203	This provision would create a new tax credit for the sale or mixture of sustainable aviation fuel starting in 2023. The tax credit would have a base amount of $1.25 per gallon, with a supplemental credit amount of $0.01 per gallon for each percentage point by which the lifecycle greenhouse gas emissions reduction percentage for the fuel exceeds 50% (with a maximum supplemental credit of $0.50 per gallon, making the maximum potential per gallon credit $1.75). Sustainable aviation fuel is defined as liquid fuel that (1) meets the requirements of either ASTM International Standard D7566 or the Fischer Tropsch provisions of ASTM International Standard D1655, Annex A1; (2) is not derived from coprocessing an applicable material with a feedstock which is not biomass; (3) is not derived from palm fatty acid distillates or petroleum; and (4) has been certified to achieve at least a 50% lifecycle greenhouse gas reduction percentage as defined according to the most recent Carbon Offsetting and Reduction Scheme for International Aviation adopted by the International Civil Aviation Organization and agreed to by the United States (or a similar methodology which satisfies criteria in the Clean Air Act Section 211(o)(1)(H)), as compared with petroleum-based jet fuel. The sustainable aviation fuel credit would require claimants to be registered with the Secretary of the Treasury, and could be used to offset fuel excise tax liability or, in the case of insufficient fuel excise tax liability, be received as a payment. Like the tax credit for biodiesel and renewable diesel, there would be a coordinated income tax credit. Credit amounts would be included in a taxpayer's gross income for income tax purposes. The $1.00 per gallon tax credit for aviation fuel produced from biodiesel (under Section 40A) would terminate after December 31, 2022. The credit would expire after December 31, 2024.	For background, see: • CRS Report R47171, *Sustainable Aviation Fuel (SAF): In Brief*, by Kelsi Bracmort and Molly F. Sherlock.
Clean Hydrogen Section 13204	This provision would create a new credit for the qualified production of clean hydrogen. The credit would be available for qualified clean hydrogen produced at a	For background, see • CRS Report R45171, *Registered*

Section Title	Description	CRS Resources
	qualifying facility during the facility's first 10 years of operation. The base credit amount would be $0.60 per kilogram (kg) times the applicable percentage. Credit amounts would be indexed for inflation. The applicable percentage would be determined by the lifecycle greenhouse gas emissions rate achieved in producing clean hydrogen. The applicable percentage would be 100% for hydrogen achieving a lifecycle greenhouse gas emissions rate of less than 0.45 kilograms of carbon dioxide equivalent (CO_2e) per kg. The applicable percentage would be 33.4% for hydrogen achieving a lifecycle greenhouse gas emission rate of less than 1.5 kilograms of CO_2e per kg (but not less than 0.45 kilograms). For hydrogen with a lifecycle greenhouse gas emission rate of less than 2.5 kgs of CO_2e per kg (but not less than 1.5), the applicable percentage would be 25%, and for hydrogen with a lifecycle greenhouse gas emissions rate of less than 4 kgs of CO_2e per kg (but not less than 2.5), the applicable percentage would be 20%. The credit would be five times the base credit amount (i.e., up to $3.00 per kg) if the clean hydrogen is produced at a facility that meets prevailing wage and registered apprenticeship requirements. The provision provides that for facilities financed with tax-exempt bonds, the credit amount would be reduced by the lesser of (1) 15%; or (2) the fraction of the proceeds of a tax-exempt obligation used to finance the project over the aggregate amount of the project's financing costs. To qualify for the credit, new facilities must begin construction before January 1, 2033. Facilities existing before January 1, 2023, would be able to qualify based on the date that modifications to their facility required to produce clean hydrogen are placed into service. Taxpayers may claim the PTC for electricity produced from renewable resources by the taxpayer if the electricity is used at a qualified clean hydrogen facility to produce qualified clean hydrogen. Taxpayers could elect to claim the energy investment tax credit (ITC) in lieu of the clean hydrogen production credit. Taxpayers could not claim credits for clean hydrogen produced at facilities that claimed credits for carbon capture under Section 45Q. The provision would terminate the alternative fuel excise tax credit for hydrogen.	*Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.
Part 3—Clean Energy and Efficiency Incentives for Individuals		
Extension, Increase, and Modifications of Nonbusiness Energy Property Credit Section 13301	Current law provides a 10% tax credit for qualified energy-efficiency improvements and expenditures for residential energy property on a taxpayer's primary residence through 2021. The credit is subject to a $500 per taxpayer lifetime limit. This provision would extend the tax credit through December 31, 2032, and make additional modifications. The proposed modifications would increase the credit rate to 30% with an annual per-taxpayer limit of $1,200 and a $600 per-item limit. For geothermal and air source	For background, see • CRS Report R42089, *Residential Energy Tax Credits: Overview and Analysis*, by Margot L. Crandall-Hollick and Molly F. Sherlock. • CRS Report R46451, *Energy Tax Provisions*

Section Title	Description	CRS Resources
	heat pumps and biomass stoves, there would be an annual credit limit of $2,000. Limits for expenditures on windows and doors would also be increased. Biomass stoves would be made eligible for tax credits. Required energy-efficiency standards would be modified, and changed to update over time without additional legislative action. Qualifying building envelope components would no longer include roofs, but would include air sealing insulation. Improvements to or replacements of panelboards, sub-panelboards, branch circuits, or feeders used with qualifying property would also be credit-eligible costs. The credit would be allowed for expenditures made on any dwelling unit used by the taxpayer (not limited to primary residences). A 30% credit, up to $150, would be allowed for home energy audits. Treasury would be given the authority to treat errors related to this section as mathematical or clerical errors. Starting in 2025, taxpayers would be required to submit a product identification number to claim the tax credit. The credit would be renamed the energy efficient home improvement credit.	*Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples.
Residential Clean Energy Credit Section 13302	Current law provides a tax credit for the purchase of solar electric property, solar water heating property, fuel cells, geothermal heat pump property, small wind energy property, and qualified biomass fuel property. The credit rate is 26% through 2022 (it was 30% through 2019), and is scheduled to be reduced to 22% in 2023 before expiring at the end of that year. This provision would extend the credit through December 31, 2034, restoring the 30% credit rate through 2032, and then reducing the credit rate to 26% in 2033 and 22% in 2034. Qualified battery storage technology would be added to the list of eligible property. The credit would be renamed the residential clean energy credit.	For background, see • CRS Report R42089, *Residential Energy Tax Credits: Overview and Analysis*, by Margot L. Crandall-Hollick and Molly F. Sherlock. • CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples.
Energy Efficient Commercial Buildings Deduction Section 13303	Under current law, a permanent deduction of up to $1.80 per square foot is allowed for certain energy-saving commercial building property installed as part of (1) the interior lighting system; (2) the heating, cooling, ventilation, or hot water system; or (3) the building envelope. This provision would update efficiency requirements, providing that a qualifying building must increase its efficiency relative to a reference building by 25%. The deduction would be set at $0.50 per square foot, and increased by $0.02 for each percentage point by which the certified efficiency improvements reduce energy and power costs, with a maximum amount of $1.00 per square foot. For projects that meet prevailing wage and registered apprenticeship requirements, the base amount is $2.50, which would be increased by $0.10 for each percentage point increase in energy efficiency, with a maximum amount of $5.00 per square foot. The maximum deduction amount would be the total deduction	For background, see • CRS Committee Print CP10004, *Tax Expenditures: Compendium of Background Material on Individual Provisions — A Committee Print Prepared for the Senate Committee on the Budget, 2020*, by Jane G. Gravelle et al. (pp. 99-104). • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal*

Section Title	Description	CRS Resources
	a building can claim less deductions claimed with respect to the building in the preceding three years. Taxpayers making energy-efficiency retrofits that are part of a qualified retrofit plan on a building that is at least five years old would be able to deduct their adjusted basis in the retrofit property (so long as that amount does not exceed a per-square foot value determined on the basis of energy usage intensity). To qualify, retrofit plans must be expected to reduce a building's energy use intensity by at least 25%. Any tax-exempt entity would be allowed to allocate the deduction to the designer of the building or retrofit plan.	*Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.
Extension, Increase, and Modifications of New Energy Efficient Home Credit Section 13304	Under current law, through 2021, a tax credit is available for eligible contractors for building and selling qualifying energy-efficient new homes. The credit is equal to $2,000, with certain manufactured homes qualifying for a $1,000 credit. This provision would extend the energy-efficient new home credit through December 31, 2032, and increase and modify the credit amount. For homes acquired after 2021, a $2,500 credit would be available for new homes that meet certain Energy Star efficiency standards, and a $5,000 credit would be available for new homes that are certified as zero-energy ready homes. Multifamily dwellings that meet certain Energy Star efficiency standards would be eligible for a $500 credit per unit, with a $1,000 per unit credit available for eligible zero-energy ready multifamily dwellings. The credits for multifamily dwelling units would be increased to $2,500 and $5,000, respectively, if the taxpayer ensures that the laborers and mechanics employed by contractors and subcontractors in the construction of the residence are paid prevailing wages. Taxpayers claiming the low-income housing tax credit would not have to reduce their basis for credits claimed under this section.	For background, see • CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L. Crandall-Hollick, and Donald J. Marples. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.
Part 4—Clean Vehicles		
Clean Vehicle Credit Section 13401	Buyers of qualifying plug-in electric vehicles (EVs) may be able to claim a nonrefundable tax credit of up to $7,500 under current law. The tax credit phases out once a vehicle manufacturer has sold 200,000 qualifying vehicles. Current law also allows, through 2021, a tax credit of up to $8,000 for fuel cell vehicles (the base credit amount is $4,000, with up to an additional $4,000 available based on fuel economy). Heavier fuel cell vehicles qualify for up to a $40,000 credit. This provision would modify the tax credit for plug-in electric vehicles, allowing certain clean vehicles to qualify and eliminating the current per manufacturer limit. The credit would be renamed the clean vehicle credit. The modified credit for clean vehicles would be $3,750 for any vehicle meeting the critical minerals requirement, and $3,750 for any vehicle meeting the battery components requirement. The maximum credit per vehicle would be $7,500. Clean vehicles would include plug-in electric vehicles with a battery capacity of at least	For background, see • CRS In Focus IF11017, *The Plug-In Electric Vehicle Tax Credit*, by Molly F. Sherlock. • CRS Report R46864, *Alternative Fuels and Vehicles: Legislative Proposals*, by Melissa N. Diaz. • CRS Report R46231, *Electric Vehicles: A Primer on Technology and Selected Policy Issues*, by Melissa N. Diaz.

Section Title	Description	CRS Resources
	7 kilowatt hours and fuel cell vehicles. Qualifying vehicles would include those that had final assembly occur in North America. Sellers would be required to provide taxpayer and vehicle information to the Treasury for tax credit eligible vehicles. Only vehicles made by qualified manufacturers, who have written agreements with and provide periodic reports to the Treasury, could qualify. For vehicles placed in service after 2023, qualifying vehicles would not include any vehicle with battery components that were manufactured or assembled by a foreign entity of concern (as defined in 42 U.S.C. §18741). For vehicles placed in service after 2024, qualifying vehicles would not include any vehicle in which applicable critical minerals in the vehicle's battery were from a foreign entity of concern. Taxpayers would be required to include the vehicle identification number (VIN) on their tax return to claim a tax credit. To receive the $3,750 critical minerals portion of the credit, the vehicle's battery must contain a threshold percentage (in value) of critical minerals that were extracted or processed in a country with which the United States has a free trade agreement, or recycled in North America. The threshold percentage would be 40% through 2023, increasing to 50% in 2024, 60% in 2025, 70% in 2026, and 80% after 2026. To receive the $3,750 battery components portion of the credit, the percentage of the battery's components manufactured or assembled in North America would have to meet threshold amounts. For vehicles placed in service through 2023, the percentage would be 50%. The percentage increases to 60% for 2024 and 2025, 70% for 2026, 80% for 2027, 90% for 2028, and 100% after 2028. The credit would be disallowed for certain higher-income taxpayers. Specifically, no credit would be allowed if the current year or preceding year's modified AGI exceeds $300,000 for married taxpayers ($225,000 in the case of head of household filers; $150,000 in the case of other filers). Credits would only be allowed for vehicles that have a manufacturer's suggested retail price of no more than $80,000 for vans, SUVs, or pickup trucks, and $55,000 for other vehicles. Taxpayers would be allowed to claim the credit for one vehicle per year. Starting in 2024, taxpayers purchasing eligible vehicles could elect to transfer the tax credit to the dealer, so long as the dealer meets registration, disclosure, and other requirements. The Secretary of the Treasury is directed to establish a program to make advance payments to dealers for transferred credits. Amounts provided as direct spending would be grossed-up (increased) by 6.0445%. The credit would not apply to vehicles acquired after December 31, 2032.	
Credit for Previously-Owned Clean Vehicles	This provision would create a new tax credit for buyers of previously owned qualified clean (plug-in electric and	For background, see • CRS In Focus IF11017, *The Plug-In Electric*

Section Title	Description	CRS Resources
Section 13402	fuel cell) vehicles. The credit would be up to $4,000 limited to 30% of the vehicle purchase price. The credit would be disallowed for taxpayers above modified AGI thresholds. Married taxpayers filing a joint return could not claim the credit if their modified AGI was above $150,000 ($112,500 in the case of head of household filers; $75,000 in the case of other filers). The taxpayer's modified AGI would be the lesser of modified AGI in the taxable year or prior year. Credits would only be allowed for vehicles with a sale price of $25,000 or less with a model year that is at least two years earlier than the calendar year in which the vehicle is sold. This credit could only be claimed for vehicles sold by a dealer and on the first transfer of a qualifying vehicle. Taxpayers could only claim this credit once every three years and would be required to include the VIN on their tax return to claim a tax credit. Starting in 2024, taxpayers purchasing eligible vehicles could elect to transfer the tax credit to the dealer, so long as the dealer meets registration, disclosure, and other requirements. Amounts provided as direct spending would be grossed-up (increased) by 6.0445%. The credit would not apply to vehicles acquired after December 31, 2032.	*Vehicle Tax Credit*, by Molly F. Sherlock. • CRS Report R46864, *Alternative Fuels and Vehicles: Legislative Proposals*, by Melissa N. Diaz. • CRS Report R46231, *Electric Vehicles: A Primer on Technology and Selected Policy Issues*, by Melissa N. Diaz.
Qualified Commercial Clean Vehicles Section 13403	This provision would create a new tax credit for qualified commercial clean vehicles placed in service by the taxpayer during the year. The credit would be the lesser of (1) 15% of the vehicle's cost (30% for vehicles not powered by a gasoline or diesel internal combustion engine); or (2) the incremental cost of the vehicle relative to a comparable vehicle. Credit amounts cannot exceed $7,500 for vehicles weighing less than 14,000 pounds, or $40,000 otherwise. Eligible vehicles would have a battery capacity of not less than 15 kilowatt hours (7 kilowatt hours in the case of vehicles weighing less than 14,000 pounds) and be charged by an external source of electricity. Mobile machinery and qualified commercial fuel cell vehicles would also be eligible for this credit. Qualifying vehicles must be depreciable property. Only vehicles made by qualified manufacturers, who have written agreements with and provide periodic reports to the Treasury, could qualify. Taxpayers would be required to include the VIN on their tax return to claim a tax credit. Tax-exempt entities would have the option of electing to receive direct payments. The credit would not apply to vehicles acquired after December 31, 2032.	
Alternative Fuel Refueling Property Credit Section 13404	Current law allows, through 2021, a tax credit for the cost of any qualified alternative fuel vehicle refueling property installed by a business or at a taxpayer's principal residence. The credit is equal to 30% of these costs, limited to $30,000 for businesses at each separate location with qualifying property, and $1,000 for residences. This provision would extend the credit	For background, see • CRS Report R46451, *Energy Tax Provisions Expiring in 2020, 2021, 2022, and 2023 ("Tax Extenders")*, by Molly F. Sherlock, Margot L.

Section Title	Description	CRS Resources
	through December 31, 2032, and make additional modifications. For business property (property subject to depreciation), the credit would be extended at a rate of 6% (30% if prevailing wage and registered apprenticeship requirements were met), with the credit limit increased to $100,000. The definition of qualifying property would be modified to include bidirectional charging equipment. The credit could also be claimed for electric charging stations for two- and three-wheeled vehicles that are intended for use on public roads. Starting in 2023, charging or refueling property would only be eligible if it is placed in service within a low-income or rural census tract.	Crandall-Hollick, and Donald J. Marples. • CRS Report R46864, *Alternative Fuels and Vehicles: Legislative Proposals*, by Melissa N. Diaz. • CRS Report R46231, *Electric Vehicles: A Primer on Technology and Selected Policy Issues*, by Melissa N. Diaz. • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.
Part 5—Investment in Clean Energy Manufacturing and Energy Security		
Extension of the Advanced Energy Project Credit Section 13501	This provision would provide additional allocations of the qualified advanced energy manufacturing tax credit, which is a 30% tax credit for investments in projects that reequip, expand, or establish certain energy manufacturing facilities. The American Recovery and Reinvestment Act (P.L. 111-5) provided $2.3 billion in allocations, which have been fully allocated. An additional $10 billion in allocations would be provided with at least $4 billion to be allocated to energy communities (as defined in the extended PTC, Section 13101) or projects not located in census tracts in which projects having received prior allocations under Section 48C are located. The definition of qualifying advanced energy projects would be amended such that it would include projects that reequip, expand, or establish a manufacturing or industrial facility for the production or recycling of renewable energy property; energy storage systems and components; grid modernization equipment and components; property designed to remove, use, or sequester carbon oxide emissions; equipment designed to refine, electrolyze, or blend any fuel, chemical, or product which is renewable or low-carbon and low-emission; property designed to produce energy conservation technologies; electric or fuel-cell vehicles, including technologies, components, or materials for such vehicles and the associated charging infrastructure; hybrid vehicles weighing less than 14,000 pounds, including technologies, components, or materials for such vehicles; which reequips an industrial manufacturing facility with	For background, see • CRS Committee Print CP10004, *Tax Expenditures: Compendium of Background Material on Individual Provisions — A Committee Print Prepared for the Senate Committee on the Budget, 2020*, by Jane G. Gravelle et al. (pp. 221-224). • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.

Section Title	Description	CRS Resources
	equipment designed to reduce greenhouse gas emissions by at least 20%; or which reequips, expands, or establishes an industrial facility for the processing, refining or recycling of critical materials. The base rate for the credit would be 6%, with the 30% credit rate allowed for projects meeting prevailing wage and registered apprenticeship requirements. The Secretary of the Treasury would be directed to establish a program to award credits to qualifying advanced energy project sponsors. Applicants accepting certifications for credits would have two years to provide evidence that the requirements of the certification have been met and to place property in service.	
Advanced Manufacturing Production Credit Section 13502	This provision would create a new production tax credit that could be claimed for the domestic production and sale of qualifying solar and wind components. Credits for solar components would include (1) for a thin film photovoltaic cell or crystalline photovoltaic cell, 4 cents per direct current watt of capacity; (2) for photovoltaic wafers, $12 per square meter; (3) for solar grade polysilicon, $3 per kilogram; (4) for polymeric backsheet, 40 cents per square meter; and (5) for solar modules, 7 cents per direct current watt of capacity. For wind energy components, if the component is an offshore wind vessel, the credit amount would be 10% of the sales price. Otherwise, credits for wind components would be computed as an applicable amount times the total rated capacity of the completed wind turbine for which the component was designed. The applicable amount would be 2 cents for blades, 5 cents for nacelles, 3 cents for towers, 2 cents for fixed platform offshore wind foundations, and 4 cents for floating platform offshore wind foundations. The credit for torque tubes and longitudinal purlin would be $0.87 per kg, and the credit for structural fasteners would be $2.28 per kg. The credit for inverters would be based on the inverter's capacity, with different types of inverters eligible for specified credit amounts ranging from 1.5 cents to 11 cents per watt. For electrode active materials, the credit would be 10% of the production cost. Battery cells could qualify for a credit of $35 per kilowatt hour of capacity, and battery modules could qualify for a credit of $10 per kilowatt hour of capacity (or $45 in the case of a battery module which does not use battery cells). A credit of 10% would also be available for the production of critical minerals. The credit would phase out for components sold after December 31, 2029. Components sold in 2030 would be eligible for 75% of the full credit amount. Components sold in 2031 and 2032 would be eligible for 50% and 25% of the full credit amount, respectively. No credit would be available for components sold after December 31, 2032. The phaseout would not apply to the production of critical minerals.	For background, see • CRS Insight IN11980, *Offshore Wind Provisions in the Inflation Reduction Act*, by Laura B. Comay, Corrie E. Clark, and Molly F. Sherlock.

Section Title	Description	CRS Resources
	The credit could not be claimed for components produced at a facility for which a credit was claimed under Section 48C.	
Part 6—Superfund		
Reinstatement of Superfund Section 13601	This provision would permanently reinstate the Hazardous Substance Superfund financing rate for certain excise taxes, but would not reauthorize the Superfund special environmental tax on corporate income that also once financed this trust fund. This provision would permanently reinstate Superfund excise taxes on domestic crude oil and imported petroleum products at the rate of 16.4 cents per barrel in 2023, with adjustments for inflation annually thereafter. The previous tax rate was 9.7 cents per barrel when this tax last expired at the end of 1995. Generally, the tax is paid by refineries that receive crude oil or by the person using or importing a petroleum product. The Infrastructure Investment and Jobs Act (P.L. 117-58) separately renewed other excise taxes that contribute to the Superfund. P.L. 117-58 increased the tax rate on domestically produced chemical feedstocks and imported chemical derivatives and renewed those taxes from July 1, 2022, through December 31, 2031. P.L. 117-58 also removed the statutory link between the dates of applicability of the crude oil and chemical products taxes. Revenues from the excise tax finance the Hazardous Substance Superfund Trust Fund. Borrowing would be authorized through repayable advances from the General Fund of the U.S. Treasury until the end of 2032.	For background, see • CRS In Focus IF11982, *Superfund Tax Legislation in the 117th Congress*, by Anthony A. Cilluffo and David M. Bearden. • CRS Report R41039, *Comprehensive Environmental Response, Compensation, and Liability Act: A Summary of Superfund Cleanup Authorities and Related Provisions of the Act*, by David M. Bearden.
Part 7—Incentives for Clean Electricity and Clean Transportation		
Clean Electricity Production Credit Section 13701	This provision would create a new clean electricity production tax credit (PTC). This new PTC would be for the sale of domestically produced electricity with a greenhouse gas emissions rate not greater than zero. To qualify for a tax credit, electricity would need to be produced at a qualifying facility placed in service after December 31, 2024. The base PTC amount would be 0.3 cents per kWh, with the tax credit amount increased to 1.5 cents per kWh for facilities that pay prevailing wages and meet registered apprenticeship requirements (0.5 cents and 2.5 cents, respectively, in 2021, applying the inflation adjustment factor; the amounts would be adjusted for inflation annually). Facilities with a maximum net output of less than 1 megawatt and that begin before 60 days after the Secretary of the Treasury publishes guidance on the wage and registered apprenticeship requirements would also qualify for the full 1.5 cents per kWh amount. The PTC would be available for electricity produced during the facility's first 10 years of operation. The credit amount would be increased by 10% for electricity produced in energy communities (as defined for	For background, see • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro. • CRS Insight IN11983, *Proposed Tax Preference for Domestic Content in Energy Infrastructure*, by Christopher D. Watson and Molly F. Sherlock.

Section Title	Description	CRS Resources
	the purposes of the increased credit amount under the PTC and ITC). The provision would provide that for facilities financed with tax-exempt bonds, the credit amount is reduced by the lesser of (1) 15%; or (2) the fraction of the proceeds of a tax-exempt obligation used to finance the project over the aggregate amount of the project's financing costs. A 10% domestic content bonus would be available for electricity produced at facilities that certify that certain steel, iron, and manufactured products used in the facility were domestically produced. The ability to claim the credit as direct pay would be subject to meeting domestic content requirements. Taxpayers would not be able to claim the clean electricity production credit if the facility or electricity produced from the facility claimed certain other energy-related investment or production tax credits. Taxpayers would choose between the clean electricity PTC and ITC, and could not claim both. The tax credit would phase out when emissions reduction target levels are achieved or after 2032 (the later of the two). The emissions target phaseout would begin after the calendar year in which greenhouse gas emissions from the electric power sector are equal to or less than 25% of 2022 electric power sector emissions. Once phaseout begins, the full credit amount would remain available for facilities that begin construction the following year. The credit amount for facilities beginning construction in the second year would be 75% of the full credit amount. This would be reduced to 50% for facilities beginning construction in the third year, and zero afterward.	
Clean Electricity Investment Credit Section 13702	This provision would create a new clean electricity investment tax credit (ITC). This new ITC would be for investment in qualifying zero-emissions electricity generation facilities or energy storage technology. Costs of interconnection property would be eligible for clean electricity projects smaller than 5 megawatts. This credit would be available for facilities and property placed in service after December 31, 2024. The base ITC amount would be 6%, with the tax credit rate increased to 30% for facilities that pay prevailing wages and meet registered apprenticeship requirements. Facilities with a maximum net output of less than 1 megawatt and that begin before 60 days after the Secretary of the Treasury publishes guidance on the wage and registered apprenticeship requirements would also qualify for the full 30% amount. The clean electricity ITC is increased by one-third (2 percentage points or 10 percentage points) for property placed in service in an energy community (as defined above for the purposes of the clean electricity PTC). Similarly, a 10 percentage point domestic content bonus also applies for the clean electricity ITC. The ability to claim the credit as direct pay would be subject to meeting domestic content requirements.	For background, see • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro. • CRS Insight IN11983, *Proposed Tax Preference for Domestic Content in Energy Infrastructure*, by Christopher D. Watson and Molly F. Sherlock.

Section Title	Description	CRS Resources
	The provision would provide that for facilities financed with tax-exempt bonds, the credit amount is reduced by the lesser of (1) 15%; or (2) the fraction of the proceeds of a tax-exempt obligation used to finance the project over the aggregate amount of the project's financing costs. Taxpayers would not be able to claim the clean electricity production credit if the facility or electricity produced from the facility claimed certain other energy-related investment or production tax credits. Taxpayers would choose between the clean electricity PTC and ITC, and could not claim both. This provision would also allow for the annual allocation of 1.8 gigawatts for "environmental justice solar and wind capacity" credits. Taxpayers receiving a capacity allocation may be entitled to tax credits in addition to otherwise allowed clean electricity ITCs. Specifically, projects receiving an allocation that are located in a low-income community or on Indian land would be eligible for a 10 percentage point bonus investment tax credit, while projects that are part of a low-income residential building project or qualified low-income economic benefit project would be eligible for a 20 percentage point bonus investment credit. Qualifying clean electricity projects would include those with a nameplate capacity of 5 megawatts or less (other than facilities producing electricity through combustion or gasification). Facilities receiving an allocation would be required to have the facility placed in service within four years. The clean electricity ITC would phase out according to the same schedule as would apply to the clean electricity PTC.	
Cost Recovery for Qualified Facilities, Qualified Property, and Energy Storage Technology Section 13703	This provision would provide that any facility qualifying for the clean electricity PTC or any facility or property qualifying for the clean electricity ITC would be treated as 5-year property under the modified accelerated cost recovery system (MACRS), making it so that cost recovery for renewable energy investments would be generally similar to current law. This provision would apply to facilities and property placed in service after December 31, 2024.	
Clean Fuel Production Credit Section 13704	This provision would create a tax credit for domestic clean fuel production starting in 2025. The tax credit per gallon of transportation fuel would be calculated as the applicable amount multiplied by the emissions factor of the fuel. To qualify, the fuel must be produced by the taxpayer at a qualified facility (excluding facilities that receive credits for producing clean hydrogen or carbon oxide sequestration, or the investment credit for energy produced in clean hydrogen facilities) and sold by the taxpayer. Qualified producers must be registered with the IRS. The "applicable amount" would be determined by the type of fuel and the producer's labor practices. The base credit amount for zero-emissions fuels would be $0.20 for nonaviation fuel and $0.35 for aviation fuel. If the	For background, see • CRS Report R47171, *Sustainable Aviation Fuel (SAF): In Brief*, by Kelsi Bracmort and Molly F. Sherlock. • CRS Report R45171, *Registered Apprenticeship: Federal Role and Recent Federal Efforts*, by Benjamin Collins. • CRS In Focus IF11927, *Federally Funded*

Section Title	Description	CRS Resources
	producer meets prevailing wage and registered apprenticeship requirements, then the applicable amount would be $1.00 for nonaviation fuel and $1.75 for aviation fuel. These amounts would be adjusted annually for inflation. The "emissions factor" would be calculated according to the following formula: [(50 kilograms of CO2-equivalent (CO2e) global warming potential per metric million British Thermal Units (mmBTU) – emissions rate of fuel produced) / 50 kilograms of CO2e per mmBTU]. The Treasury Secretary would publish tables of emissions rates for various fuel types that would be used in the calculation. Qualifying transportation fuel would be fuel with an emissions rate not greater than 50 kilograms of CO2e per mmBTU. The credit would not be available for transportation fuel sold after December 31, 2027.	*Construction and the Payment of Locally Prevailing Wages*, by David H. Bradley and Jon O. Shimabukuro.
Part 8—Credit Monetization and Appropriations		
Elective Payment for Energy Property and Electricity Produced from Certain Renewable Resources, Etc. Section 13801	This provision would allow certain organizations, generally tax-exempt entities including state and local governments and Indian tribal governments, to treat certain tax credit amounts as payments of tax. Payments in excess of tax liability can be refunded to these organizations, allowing the credits to be received as "direct pay." This direct payment would be allowed for the Section 30C credit for alternative fuel refueling property, the Section 45 renewable electricity production credit, the Section 45Q carbon oxide sequestration credit, the new Section 45U zero-emission nuclear power production credit; the new Section 45V clean hydrogen production credit; in the case of certain tax-exempt entities, the new Section 45W credit for qualified commercial vehicles; the new Section 45X advanced manufacturing production credit; the new Section 45Y clean electricity production credit; the new Section 45Z clean fuel production credit; the Section 48 energy investment tax credit, and the Section 48C qualifying advanced energy project credit; and the new Section 48D clean electricity investment credit. Taxpayers who are not tax-exempt entities would be allowed to elect direct pay for the clean hydrogen, carbon oxide sequestration, and advanced manufacturing production credits for the first five years starting with the year a facility is placed in service. This election cannot be made after December 31, 2032. This provision would not apply to territories with mirror-code tax systems. Taxpayers who are not tax-exempt entities would be allowed a one-time transfer of these tax credits. Any payments received in exchange for the transfer of credits would be excluded from income, and any amounts paid to obtain a transferred credit could not be deducted from income. Credits that could be transferred would also be given extended carryback and carryforward periods. The carryback period for these credits would be extended from 1 to 3 years, and the carryforward period extended from 20 to 22 years.	For background, see • CRS Report R45693, *Tax Equity Financing: An Introduction and Policy Considerations*, by Mark P. Keightley, Donald J. Marples, and Molly F. Sherlock. • CRS Insight IN11983, *Proposed Tax Preference for Domestic Content in Energy Infrastructure*, by Christopher D. Watson and Molly F. Sherlock.

Section Title	Description	CRS Resources
Part 9—Other Provisions		
Permanent Extension of Tax Rate to Fund Black Lung Disability Trust Funds Section 13901	Under current law, an excise tax is imposed on coal from mines in the United States. The tax rate depends on how the coal is mined. The current rates are $0.50 per ton for coal from underground mines and $0.25 per ton for coal from surface mines, with both limited to 2% of the sales price. The Black Lung excise tax is intended to fund benefits for U.S. coal miners who develop Black Lung disease as a result of working in coal mines. Temporary, higher rates of $1.10 per ton of coal from underground mines and $0.55 per ton of coal from surface mines, limited to 4.4% of the sales price, have applied for much of the time since 1986. They most recently applied from the beginning of 2020 through the end of 2021. This provision would permanently extend the higher rates.	For background, see • CRS Report R45261, *The Black Lung Program, the Black Lung Disability Trust Fund, and the Excise Tax on Coal: Background and Policy Options*, by Scott D. Szymendera and Molly F. Sherlock.
Increase in Research Credit Against Payroll Tax for Small Business Section 13902	Under current law, businesses are allowed a credit against income tax that is based on their qualified research expenses. The credit is calculated as the amount of qualified research expenses above a base amount that is meant to represent the amount of research expenditures in the absence of the credit. Some small businesses may not have a large enough income tax liability to take advantage of their research credit. Current law allows a small business, defined as a business with less than $5 million in gross receipts and that is under five years old, to apply up to $250,000 of the research credit toward its Social Security payroll tax liability. This provision would allow an additional credit of up to $250,000 against Medicare Hospital Insurance tax for taxable years beginning after December 31, 2022. The credit could not exceed the tax imposed for any calendar quarter, with unused amounts of the credit carried forward.	For background, see • CRS Report RL31181, *Federal Research Tax Credit: Current Law and Policy Issues*, by Gary Guenther. • CRS Report R47062, *Payroll Taxes: An Overview of Taxes Imposed and Past Payroll Tax Relief*, by Anthony A. Cilluffo and Molly F. Sherlock.
Reinstatement of Limitation Rules for Deduction for State and Local, etc., Taxes; Extension of Limitation on Excess Business Losses of Noncorporate Taxpayers Section 13903	This provision would reinstate the current-law expiration date of the state and local tax (SALT) limitation enacted in Section 13904 of the bill. In other words, the expiration date would remain 2025, as under current law. The provision would also extend the limitation on excess business losses of noncorporate taxpayers. Businesses are generally permitted to carry over a net operating loss (NOL) to certain past and future years. Under the passive loss rules, individuals and certain other taxpayers are limited in their ability to claim deductions and credits from passive trade and business activities, although unused deductions and credits may generally be carried forward to the next year. Similarly, certain farm losses may not be deducted in the current year, but can be carried forward to the next year. For taxpayers other than C corporations, a deduction in the current year for excess business losses is temporarily disallowed (through 2026) and such losses are treated as a NOL carryover to the following year. An excess	For background, see • CRS Insight IN11296, *Tax Treatment of Net Operating Losses (NOLs) in the Coronavirus Aid, Relief, and Economic Security (CARES) Act*, by Jane G. Gravelle. • CRS Report R46377, *The Tax Treatment and Economics of Net Operating Losses*, by Mark P. Keightley.

Section Title	Description	CRS Resources
	business loss is the amount that a taxpayer's aggregate deductions attributable to trades and businesses exceed the sum of (1) aggregate gross income or gain attributable to such activities and (2) $250,000 ($500,000 if married filing jointly), adjusted for inflation. For partnerships and S corporations, this provision was applied at the partner or shareholder level. This provision would extend the temporary limitation through 2028.	
Removal of Harmful Small Business Taxes; Extension of Limitation of Deduction for State and Local, etc., Taxes Section 13904	In addition to the modification noted in Section 10101 above, this provision would have extended the $10,000 state and local tax (SALT) limitation from 2025 through 2026. However, the SALT change would effectively be reversed by changes made in Section 13903 of the bill.	For background, see • CRS Report R46246, *The SALT Cap: Overview and Analysis*, by Grant A. Driessen and Joseph S. Hughes.

Source: CRS analysis of the legislative text of the Senate amendment to H.R. 5376, "Inflation Reduction Act of 2022," as posted on the House Rule Committee Website at https://rules.house.gov/bill/117/hr-5376-sa.

Notes: Energy provisions that extend expiring provisions are generally effective in 2022, with new provisions generally effective in 2023. Exceptions are noted. Sections 13903 and 13904 were added during Senate consideration of the bill. The changes that would be made by the provisions are permanent, unless otherwise noted. Within the description, "Section" citations refer to the section within the Internal Revenue Code (IRC), 26 U.S.C., unless otherwise noted. Section 13802 would provide appropriations of $500 million to remain available until September 30, 2031, for the IRS to carry out this subtitle.

Table 5. Estimated Budgetary Effect of the Revenue Provisions of the "Inflation Reduction Act of 2022"

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
SUBTITLE A—DEFICIT REDUCTION											
Part 1—Corporate Tax Reform	—	34,679	34,258	22,039	17,702	18,699	20,798	22,756	24,658	26,659	222,248
Part 2—Excise Tax on Repurchase of Corporate Stock	—	5,697	7,875	8,070	8,581	8,882	8,838	8,603	8,500	8,641	73,686
Part 3—Funding the Internal Revenue Service and Improving Taxpayer Compliance	Estimates to be provided by the Congressional Budget Office (CBO)										
Total of Subtitle A	**—**	***40,376***	***42,133***	***30,109***	***26,283***	***27,581***	***29,636***	***31,359***	***33,158***	***35,300***	***295,934***
SUBTITLE B—PRESCRIPTION DRUG PRICING REFORM | SUBTITLE C—AFFORDABLE CARE ACT SUBSIDIES											
Totals of Subtitle B and C	*Estimates to be provided by the Congressional Budget Office (CBO)*										
SUBTITLE D—ENERGY SECURITY											
Part 1—Clean Electricity and Reducing Carbon Emissions											
Extension and modification of credit for electricity produced from certain renewable resources	—	-1,562	-2,183	-3,317	-4,822	-6,428	-7,677	-8,232	-8,329	-8,511	-51,062
Extension and modification of energy credit	—	-2,140	-1,559	-2,458	-5,367	-2,359	-48	-38	-9	15	-13,962
Increase in energy credit for solar facilities placed in service in connection with low-income communities	Estimated included in "Extension and modification of credit for electricity produced from certain renewable resources" and "Extension and modification of energy credit" above										
Extension and modification of credit for carbon oxide sequestration	—	-42	-303	-469	-495	-463	-429	-388	-343	-296	-3,229
Zero-emission nuclear power production credit	—	—	-2,188	-3,524	-3,710	-3,838	-3,960	-4,050	-4,279	-4,452	-30,001
Total of Part 1	**—**	***-3,744***	***-6,233***	***-9,768***	***-14,394***	***-13,088***	***-12,115***	***-12,709***	***-12,961***	***-13,243***	***-98,254***

JA723

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
Part 2—Clean Fuels											
Extension of incentives for biodiesel, renewable diesel, and alternative fuels	—	-2,776	-1,780	-1,015	—	—	—	—	—	—	-5,571
Extension of second-generation biofuel incentives	—	-24	-20	-10	—	—	—	—	—	—	-54
Sustainable aviation fuel credit	—	-10	-25	-14	—	—	—	—	—	—	-49
Credit for production of clean hydrogen	—	-131	-362	-610	-918	-1,251	-1,627	-2,082	-2,667	-3,518	-13,166
Total of Part 2	**—**	***-2,941***	***-2,187***	***-1,649***	***-918***	***-1,251***	***-1,627***	***-2,082***	***-2,667***	***-3,518***	***-18,840***
Part 3—Clean Energy and Efficiency Incentives for Individuals											
Extension, increase, and modifications of nonbusiness energy property credit	—	-1,887	-1,348	-1,324	-1,345	-1,327	-1,277	-1,301	-1,314	-1,327	-12,451
Extension of residential clean energy credit	—	-459	-1,021	-2,692	-2,770	-2,850	-2,935	-3,019	-3,092	-3,185	-22,022
Energy efficient commercial buildings deduction	—	-62	-50	-46	-42	-38	-35	-32	-30	-28	-362
Extension, increase, and modifications of new energy efficient home credit	—	-273	-193	-203	-216	-230	-241	-240	-229	-217	-2,043
Total of Part 3	**—**	***-2,681***	***-2,612***	***-4,265***	***-4,373***	***-4,445***	***-4,488***	***-4,592***	***-4,665***	***-4,757***	***-36,879***
Part 4—Clean Vehicles											
Clean vehicle credit	—	-85	-451	-557	-681	-854	-1,024	-1,155	-1,303	-1,429	-7,541
Credit for previously-owned qualified plug-in electric drive motor vehicles	—	-99	-96	-120	-132	-146	-162	-179	-197	-215	-1,347
Credit for qualified commercial clean vehicles	—	-189	-177	-228	-298	-388	-469	-539	-607	-687	-3,583
Alternative fuel refueling property credit	—	-138	-128	-145	-164	-184	-207	-231	-257	-284	-1,738

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
Total of Part 4	**—**	***-511***	***-852***	***-1,050***	***-1,275***	***-1,572***	***-1,862***	***-2,105***	***-2,365***	***-2,615***	***-14,209***
Part 5—Investment in Clean Energy Manufacturing and Energy Security											
Extension of the advanced energy project credit	—	-1,463	-1,377	-915	-926	-614	-442	-280	-196	-42	-6,255
Advanced manufacturing production credit	—	-1,755	-2,503	-2,691	-3,165	-3,563	-3,938	-4,534	-4,562	-3,921	-30,632
Total of Part 5	**—**	***-3,218***	***-3,880***	***-3,606***	***-4,091***	***-4,177***	***-4,380***	***-4,814***	***-4,758***	***-3,963***	***-36,887***
Part 6—Reinstatement of Superfund											
Total of Part 6	**—**	***902***	***1,230***	***1,271***	***1,304***	***1,336***	***1,368***	***1,402***	***1,436***	***1,470***	***11,719***
Part 7—Incentives for Clean Electricity and Clean Transportation											
Clean electricity production credit	—	—	—	—	-12	-45	-571	-1,864	-3,497	-5,215	-11,204
Clean electricity investment credit	—	—	—	-39	-57	-6,575	-10,315	-10,742	-11,264	-11,865	-50,858
Cost recovery for qualified facilities, qualified property, and energy storage technology	—	—	—	—	—	-26	-83	-134	-171	-211	-624
Clean fuel production credit	—	—	—	-641	-791	-1,177	-337	—	—	—	-2,946
Total of Part 7	**—**	**—**	**—**	***-680***	***-860***	***-7,823***	***-11,306***	***-12,740***	***-14,932***	***-17,291***	***-65,632***
Part 8—Credit Monetization and Appropriations											
Total of Part 8	***Estimates Contained in Relevant Items Above***										
Part 9—Other Provisions											
Permanent extension of tax rate to fund Black Lung Disability Trust Fund	—	103	135	131	130	130	131	132	133	134	1,159
Increase in research credit against payroll tax for small businesses	—	-16	-13	-15	-16	-18	-21	-22	-23	-24	-168

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
Limitation on excess business losses of noncorporate taxpayers extended for two years	—	—	—	—	—	17,666	26,198	9,453	-274	-284	52,759
Total of Part 9	**—**	***87***	***122***	***116***	***114***	***17,778***	***26,308***	***9,563***	***-164***	***-174***	***53,750***
Total of Subtitle D	**—**	***-12,107***	***-14,412***	***-19,631***	***-24,493***	***-13,243***	***-8,101***	***-28,076***	***-41,076***	***-44,091***	***-205,231***
NET TOTAL	**—**	**28,269**	**27,721**	**10,478**	**1,790**	**14,338**	**21,535**	**3,283**	**-7,918**	**-8,791**	**90,703**

Source: Joint Committee on Taxation, *Estimated Budgetary Effect of the Revenue Provisions of Title I -Committee on Finance, of an Amendment in the Nature of a Substitute to H.R. 5376, "An Act to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14," as Passed by the Senate on August 7, 2022, and Scheduled for Consideration by the House of Representatives on August 12, 2022,"* JCX-18-22, August 9, 2022, https://www.jct.gov/publications/2022/jcx-18-22/.

Notes: A "—" indicates no estimated budget effect.

Appendix. Inflation Reduction Act as Initially Proposed in the Senate

Table A-1. Subtitle A—Deficit Reduction

Section Title	Description	CRS Resources
Part 1—Corporate Tax Reform		
Corporate Alternative Minimum Tax Section 10101	This provision would impose a new alternative minimum tax of 15% on corporations based on financial income. It would apply to corporations with $1 billion or more in average annual earnings in the previous three years. In the case of U.S. corporations that have foreign parents, it would apply only to income earned in the United States of $100 million or more of average annual earnings in the previous three years (and apply when the international financial reporting group has income of $1 billion or more). It would apply to a new corporation in existence for less than three years based on the earnings in the years of existence. The provision would exclude Subchapter S corporations, regulated investment companies (RICs), and real estate investment trusts (REITs). The tax would apply to private equity companies. Firms that file consolidated returns would include income allocable to the firm from related firms including controlled foreign corporations (and any disregarded entities); for other related firms, dividends would be included. The provision would allow special deductions for cooperatives and Alaska Native Corporations. It would make adjustments to conform financial accounting to tax accounting for certain defined benefit pension plans. It would apply with respect to items under the unrelated business income tax for tax-exempt entities. The additional tax would equal the amount of the minimum tax in excess of the regular income tax plus the additional tax from the Base Erosion and Anti-Abuse tax. Income would be increased by federal and foreign income taxes to place income on a pretax basis. Losses would be allowed in the same manner as with the regular tax, with loss carryovers limited to 80% of taxable income. Domestic credits under the general business tax (such as the R&D credit) would be allowed to offset up to 75% of the combined regular and minimum tax. Foreign tax credits would be allowed based on the allowance for foreign taxes paid in a corporation's financial statement. A credit for additional minimum tax could be carried over to future years to offset regular tax when that tax is higher. This tax would apply to taxable years beginning after December 31, 2022.	For background, see • CRS In Focus IF12179, *The Corporate Minimum Tax Proposal*, by Jane G. Gravelle. • CRS Report R46887, *Minimum Taxes on Business Income: Background and Policy Options*, by Molly F. Sherlock and Jane G. Gravelle. • CRS Insight IN11646, *A Look at Book-Tax Differences for Large Corporations Using Aggregate Internal Revenue Service (IRS) Data*, by Molly F. Sherlock and Jane G. Gravelle.
Part 2—Closing the Carried Interest Loophole		
Modification of Rules for Partnership	Under current law, partnership interest transferred to the taxpayer in connection with the provision of services to a	For background, see

Section Title	Description	CRS Resources
Interests Held in Connection with the Performance of Services Section 10201	trade or business (carried interest) held for at least three years is taxed as a long-term capital gain. This provision would modify the tax rules surrounding "carried interest" by extending the holding period to qualify for long-term capital gains to five years for taxpayers with adjusted gross income of $400,000 or more, broadening the definition of carried interest to include partnership assets under the taxpayer's direct or indirect control, and adding additional rules for measuring the holding period (including for tiered partnerships).	• CRS Report R46447, *Taxation of Carried Interest*, by Donald J. Marples.

Source: CRS analysis of the legislative text of the "Inflation Reduction Act of 2022," as posted on the Senate Democrats website on July 27, 2022, at https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf.

Notes: Both provisions in this table are effective for taxable years beginning after December 31, 2022. The changes that would be made by these provisions are permanent. Part 3 of Subtitle A would provide additional appropriations of $79.6 billion over the next 10 years to enhance IRS service and enforcement activities. For background on IRS appropriations, see CRS In Focus IF12098, *Internal Revenue Service Appropriations, FY2023*, by Gary Guenther.

Table A-2. Subtitle B—Prescription Drug Reform

Section Title	Description	CRS Resources
Part 1—Lowering Prices Through Drug Price Negotiations		
Selected Drug Manufacturer Excise Tax Imposed During Noncompliance Period Section 11003	This provision would impose a new excise tax on drug manufacturers, producers, and importers who fail to enter into drug pricing agreements under Section 1193 of the Social Security Act, as added by the bill on selected drugs (i.e., are noncompliant with Section 1193). This excise tax would be found under the new Internal Revenue Code (IRC) Section 5000D. The excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance. The provision does not specify these rates explicitly, but instead defines an applicable percentage which equals the share of the post-tax sale price attributable to the excise tax. Specifically, the applicable percentage as defined in the statute equals tax/(tax+price) which simplifies to tax rate/(tax rate+1) with the applicable percentages being 65% for the sales of selected drugs during the first 90 days of noncompliance, 75% for sales during the 91st to 180th days of noncompliance, 85% for sales during the 181st to 270th days of noncompliance, and 95% for sales after the 270th day of noncompliance. Hence, the corresponding tax rates would be calculated as (applicable percentage)/(1-applicable percentage) and equal 185.71%, 300%, 566.67% and 1,900% respectively, depending on the duration of noncompliance. For example, if a selected drug was subject to the top tax rate of 1,900% and cost $10 pre-tax, it would cost $200 post-tax with $190 of the $200 cost (or 95%, the applicable percentage) being attributable to the excise tax. Selected drugs would be those defined in Section 1192(a) of the Social Security Act, as enacted under this bill, which are manufactured or produced in the United States or	For background, see • CRS Report R47056, *Build Back Better Act (BBBA) Health Coverage Provisions: House-Passed and Senate-Released Language*, coordinated by Vanessa C. Forsberg and Ryan J. Rosso.

Section Title	Description	CRS Resources
	entered the United States for consumption, use, or warehousing. The excise tax would not apply to drugs sold for export, and the provision addresses the refund or credit process if tax is paid. Noncompliance periods as defined in the bill would generally begin after the deadline to enter into an agreement to negotiate or renegotiate, or to agree upon a maximum price, had passed. Such periods would end when such agreement has been reached. The earliest potential noncompliance period would begin on October 2, 2023. For sales that were timed to avoid the excise tax, the Secretary of the Treasury could treat the sale as occurring during a day in a noncompliance period. Manufacturers would be prohibited from deducting excise tax payments from their federal income taxes. Internal IRS appeals would not be permitted with respect to this new excise tax. Additionally, no suit or proceeding for a refund of the tax would be permitted until the taxpayer had made full payment of the tax (including applicable interest and penalties).	

Source: CRS analysis of the legislative text of the "Inflation Reduction Act of 2022," as posted on the Senate Democrats website on July 27, 2022, at https://www.democrats.senate.gov/imo/media/doc/inflation_reduction_act_of_2022.pdf.

Notes: This provision would apply after the date of enactment to the sale of drugs during a noncompliance period. The first noncompliance period could begin on October 2, 2023. Within the description, "Section" citations refer to the section within the Internal Revenue Code (IRC), 26 U.S.C., unless otherwise noted.

Table A-3. Estimated Budgetary Effect of the Revenue Provisions of the "Inflation Reduction Act of 2022"

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
SUBTITLE A—DEFICIT REDUCTION											
Part 1—Corporate Tax Reform	—	52,618	44,000	29,738	26,464	27,191	29,697	32,160	34,463	36,808	313,138
Part 2—Closing the Carried Interest Loophole	—	1,594	1,511	1,430	1,389	1,379	1,389	1,413	1,445	1,487	13,037
Part 3—Funding the Internal Revenue Service and Improving Taxpayer Compliance	Estimates to be provided by the Congressional Budget Office (CBO)										
Total of Subtitle A	**—**	***54,212***	***45,511***	***31,168***	***27,853***	***28,570***	***31,086***	***33,573***	***35,908***	***38,295***	***326,175***
SUBTITLE B—PRESCRIPTION DRUG PRICING REFORM | SUBTITLE C—AFFORDABLE CARE ACT SUBSIDIES											
Totals of Subtitle B and C	*Estimates to be provided by the Congressional Budget Office (CBO)*										
SUBTITLE D—ENERGY SECURITY											
Part 1—Clean Electricity and Reducing Carbon Emissions											
Extension and modification of credit for electricity produced from certain renewable resources	—	-1,562	-2,183	-3,317	-4,822	-6,428	-7,677	-8,232	-8,329	-8,511	-51,062
Extension and modification of energy credit	—	-2,140	-1,559	-2,458	-5,367	-2,359	-48	-38	-9	15	-13,962
Increase in energy credit for solar facilities placed in service in connection with low-income communities	Estimated included in "Extension and modification of credit for electricity produced from certain renewable resources" and "Extension and modification of energy credit" above										
Extension and modification of credit for carbon oxide sequestration	—	-42	-303	-469	-495	-463	-429	-388	-343	-296	-3,229
Zero-emission nuclear power production credit	—	—	-2,188	-3,524	-3,710	-3,838	-3,960	-4,050	-4,279	-4,452	-30,001
Total of Part 1	**—**	***-3,744***	***-6,233***	***-9,768***	***-14,394***	***-13,088***	***-12,115***	***-12,709***	***-12,961***	***-13,243***	***-98,254***

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
Part 2—Clean Fuels											
Extension of incentives for biodiesel, renewable diesel, and alternative fuels	-104	-2,672	-1,780	-1,015	—	—	—	—	—	—	-5,571
Extension of second-generation biofuel incentives	-7	-17	-20	-10	—	—	—	—	—	—	-54
Sustainable aviation fuel credit	—	-10	-25	-14	—	—	—	—	—	—	-49
Credit for production of clean hydrogen	—	-131	-362	-610	-918	-1,251	-1,627	-2,082	-2,667	-3,518	-13,166
Total of Part 2	***-111***	***-2,830***	***-2,187***	***-1,649***	***-918***	***-1,251***	***-1,627***	***-2,082***	***-2,667***	***-3,518***	***-18,840***
Part 3—Clean Energy and Efficiency Incentives for Individuals											
Extension, increase, and modifications of nonbusiness energy property credit	-253	-1,634	-1,348	-1,324	-1,345	-1,327	-1,277	-1,301	-1,314	-1,327	-12,451
Extension of residential clean energy credit	-52	-407	-1,021	-2,692	-2,770	-2,850	-2,935	-3,019	-3,092	-3,185	-22,022
Energy efficient commercial buildings deduction	—	-62	-50	-46	-42	-38	-35	-32	-30	-28	-362
Extension, increase, and modifications of new energy efficient home credit	—	-273	-193	-203	-216	-230	-241	-240	-229	-217	-2,043
Total of Part 3	***-305***	***-2,376***	***-2,612***	***-4,265***	***-4,373***	***-4,445***	***-4,488***	***-4,592***	***-4,665***	***-4,757***	***-36,879***
Part 4—Clean Vehicles											
Clean vehicle credit	—	-85	-451	-557	-681	-854	-1,024	-1,155	-1,303	-1,429	-7,541
Credit for previously-owned qualified plug-in electric drive motor vehicles	—	-99	-96	-120	-132	-146	-162	-179	-197	-215	-1,347
Credit for qualified commercial clean vehicles	—	-189	-177	-228	-298	-388	-469	-539	-607	-687	-3,583
Alternative fuel refueling property credit	—	-138	-128	-145	-164	-184	-207	-231	-257	-284	-1,738

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
Total of Part 4	**—**	***-511***	***-852***	***-1,050***	***-1,275***	***-1,572***	***-1,862***	***-2,105***	***-2,365***	***-2,615***	***-14,209***
Part 5—Investment in Clean Energy Manufacturing and Energy Security											
Extension of the advanced energy project credit	—	-1,463	-1,377	-915	-926	-614	-442	-280	-196	-42	-6,255
Advanced manufacturing production credit	—	-1,754	-2,502	-2,690	-3,164	-3,562	-3,937	-4,533	-4,561	-3,920	-30,622
Total of Part 5	**—**	***-3,217***	***-3,879***	***-3,605***	***-4,090***	***-4,176***	***-4,379***	***-4,813***	***-4,757***	***-3,962***	***-36,877***
Part 6—Reinstatement of Superfund											
Total of Part 6	**—**	***902***	***1,230***	***1,271***	***1,304***	***1,336***	***1,368***	***1,402***	***1,436***	***1,470***	***11,719***
Part 7—Incentives for Clean Electricity and Clean Transportation											
Clean electricity production credit	—	—	—	—	-12	-45	-571	-1,864	-3,497	-5,215	-11,204
Clean electricity investment credit	—	—	—	-39	-57	-6,575	-10,315	-10,742	-11,264	-11,865	-50,858
Cost recovery for qualified facilities, qualified property, and energy storage technology	—	—	—	—	—	-26	-83	-134	-171	-211	-624
Clean fuel production credit	—	—	—	-641	-791	-1,177	-337	—	—	—	-2,946
Total of Part 7	**—**	**—**	**—**	***-680***	***-860***	***-7,823***	***-11,306***	***-12,740***	***-14,932***	***-17,291***	***-65,632***
Part 8—Credit Monetization and Appropriations											
Total of Part 8	***Estimates Contained in Relevant Items Above***										
Part 9—Other Provisions											
Permanent extension of tax rate to fund Black Lung Disability Trust Fund	—	103	135	131	130	130	131	132	133	134	1,159
Increase in research credit against payroll tax for small businesses	—	-16	-13	-15	-16	-18	-21	-22	-23	-24	-168

Provision	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-2031
Total of Part 9	—	*87*	*122*	*116*	*114*	*112*	*110*	*110*	*110*	*110*	*991*
Total of Subtitle D	*-416*	*-11,690*	*-14,411*	*-19,630*	*-24,492*	*-30,908*	*-34,298*	*-37,528*	*-40,801*	*-43,806*	*-257,980*
NET TOTAL	**-416**	**42,522**	**31,100**	**11,538**	**3,361**	**-2,338**	**-3,212**	**-3,955**	**-4,893**	**-5,511**	**68,195**

Source: Joint Committee on Taxation, *Estimated Budgetary Effect of the Revenue Provisions of Title I -Committee on Finance, of an Amendment in the Nature of a Substitute to H.R. 5376, the "Inflation Reduction Act of 2022,"* #22-2-027, July 28, 2022, https://www.finance.senate.gov/imo/media/doc/7.29.22%20Estimate%20of%20Manchin%20Schumer%20agreement.pdf.

Notes: A "—" indicates no estimated budget effect.

Author Information

Molly F. Sherlock, Coordinator
Specialist in Public Finance

Jane G. Gravelle
Senior Specialist in Economic Policy

Anthony A. Cilluffo
Analyst in Public Finance

Donald J. Marples
Specialist in Public Finance

Margot L. Crandall-Hollick
Specialist in Public Finance

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Exhibit E

JOINT COMMITTEE ON TAXATION
November 19, 2021
JCX-46-21

ESTIMATED BUDGET EFFECTS OF THE REVENUE PROVISIONS OF TITLE XIII - COMMITTEE ON WAYS AND MEANS, OF H.R. 5376, THE "BUILD BACK BETTER ACT," AS PASSED BY THE HOUSE OF REPRESENTATIVES

Fiscal Years 2022 - 2031

[Millions of Dollars]

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
SUBTITLE E - INFRASTRUCTURE FINANCING AND COMMUNITY DEVELOPMENT													
Part 1 - Low Income Housing Credit													
1. Increases in State allocations	cyba 12/31/21	-3	-20	-73	-252	-345	-359	-326	-264	-228	-213	-693	-2,083
2. Tax-exempt bond financing requirement (sunset 12/31/26)	[1]	-57	-200	-424	-736	-1,010	-1,062	-1,226	-1,291	-1,305	-1,307	-2,426	-8,617
3. Buildings designed to serve extremely low-income households	[2]	-7	-31	-75	-130	-183	-227	-275	-319	-362	-416	-426	-2,025
4. Repeal of qualified contract option	DOE	2	7	16	27	38	49	60	72	84	101	91	457
5. Modification and clarification of rights relating to building purchase	[3]	2	8	18	32	45	59	74	88	103	124	105	553
Total of Part 1 - Low Income Housing Credit		**-63**	**-236**	**-538**	**-1,058**	**-1,454**	**-1,540**	**-1,693**	**-1,715**	**-1,708**	**-1,712**	**-3,349**	**-11,716**
Part 2 - Neighborhood Homes Investment Act	**tyba 12/31/21**	**-192**	**-481**	**-1061**	**-1170**	**-1177**	**-1086**	**-494**	**-198**	**---**	**---**	**-4,082**	**-5,859**
Part 3 - Investments in Tribal Infrastructure													
1. Treatment of Indian Tribes as States with respect to bond issuance	oii cyba DOE	[4]	-1	-3	-4	-6	-8	-10	-12	-15	-17	-14	-77
2. New markets tax credit for Tribal Statistical Areas	cya 12/31/21	---	[4]	-2	-6	-13	-21	-29	-34	-37	-36	-22	-178
3. Inclusion of Indian areas as difficult development areas for purposes of certain buildings	bpisa 12/31/21	[4]	-2	-4	-8	-11	-13	-16	-18	-21	-24	-25	-117
Total of Part 3 - Investments in Tribal Infrastructure		**[4]**	**-3**	**-9**	**-18**	**-30**	**-42**	**-55**	**-64**	**-73**	**-77**	**-61**	**-372**
Part 4 - Other Provisions													
1. Possessions economic activity credit	[5]	-406	-853	-938	-1,017	-1,091	-1,169	-1,229	-1,270	-1,312	-1,356	-4,305	-10,641
2. Tax treatment of certain assistance to farmers, etc	[6]	*Estimate to be Provided by the Congressional Budget Office*											
3. Exclusion of amounts received from State-based catastrophe loss mitigation programs	tyba 12/31/20	-8	-10	-10	-11	-12	-13	-14	-15	-16	-17	-52	-126
Total of Part 4 - Other Provisions		**-414**	**-863**	**-948**	**-1,028**	**-1,103**	**-1,182**	**-1,243**	**-1,285**	**-1,328**	**-1,373**	**-4,357**	**-10,767**
TOTAL OF SUBTITLE E - INFRASTRUCTURE FINANCING AND COMMUNITY DEVELOPMENT		**-668**	**-1,583**	**-2,556**	**-3,274**	**-3,764**	**-3,850**	**-3,485**	**-3,262**	**-3,109**	**-3,162**	**-11,848**	**-28,715**

JA736

Case: 24-1820 Document: 28-3 Page: 331 Date Filed: 07/12/2024

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
SUBTITLE F - GREEN ENERGY													
THE "GROWING RENEWABLE ENERGY AND EFFICIENCY NOW (GREEN') ACT OF 2021"													
Part 1 - Renewable Electricity and Reducing Carbon Emissions													
1. Extension and modification of credit for electricity produced from certain renewable resources (sunset 12/31/26) [7]	fpisa 12/31/21 & ftcowba 12/31/21	-331	-1,087	-1,983	-3,014	-4,380	-5,846	-7,489	-9,306	-10,470	-10,981	-10,795	-54,887
2. Extension and modification of energy credit (sunset 12/31/26) [7]	generally ppisa 12/31/21	-769	-1,380	-1,565	-2,655	-5,946	-7,557	-7,587	-7,795	-8,194	-8,633	-12,315	-52,081
3. Increase in energy credit for solar facilities placed in service in connection with low-income communities (sunset 12/31/26)	1/1/22	*Estimate Included in Item F.1.2. Above*											
4. Elective payment for energy property and electricity produced from certain renewable resources, etc	tyba 12/31/21	*Estimate Included in Items F.1.1. through F.1.3. Above*											
5. Investment credit for electric transmission property (sunset 12/31/31) [7]	ppisa 12/31/21 & ptcowba 12/31/21	---	---	---	-788	-1,213	-1,213	-1,213	-2,001	-2,426	-2,425	-2,001	-11,279
6. Extension and modification of credit for carbon oxide sequestration (sunset 12/31/31)	foetcowba 12/31/21	-26	-103	-276	-426	-450	-222	-141	-161	-162	-160	-1,281	-2,128
7. Green energy publicly traded partnerships	tyba 12/31/21	-148	-126	-137	-144	-99	-50	-56	-64	-72	-80	-654	-975
8. Zero-emission nuclear power production credit (sunset 12/31/27) [7]	epasa 12/31/21 itybasd	-4,383	-2,909	-3,253	-3,524	-3,710	-3,838	-1,357	---	---	---	-17,779	-22,975
Total of Part 1 - Renewable Electricity and Reducing Carbon Emissions		**-5,657**	**-5,605**	**-7,214**	**-10,551**	**-15,798**	**-18,726**	**-17,843**	**-19,327**	**-21,324**	**-22,279**	**-44,825**	**-144,324**
Part 2 - Renewable Fuels													
1. Extension of incentives for biodiesel, renewable diesel and alternative fuels (sunset 12/31/26)	fsoua 12/31/21	-149	-2,688	-3,721	-3,802	-3,816	-1,028	---	---	---	---	-14,177	-15,205
2. Extension of second generation biofuel incentives (sunset 12/31/26)	qsgbpa 12/31/21	-10	-19	-20	-22	-24	-11	---	---	---	---	-95	-106
3. Sustainable aviation fuel credit (sunset 12/31/26)	fsoua 12/31/22	---	-7	-16	-24	-29	-13	---	---	---	---	-76	-90
4. Credit for production of clean hydrogen [7]	[8]	-70	-195	-347	-550	-785	-1,027	-1,283	-1,565	-1,681	-1,690	-1,947	-9,193
Total of Part 2 - Renewable Fuels		**-229**	**-2,909**	**-4,104**	**-4,398**	**-4,654**	**-2,079**	**-1,283**	**-1,565**	**-1,681**	**-1,690**	**-16,295**	**-24,594**
Part 3 - Green Energy and Efficiency Incentives for Individuals													
1. Extension, increase, and modifications of nonbusiness energy property credit (sunset 12/31/31)	generally ppisa 12/31/21 & apoia 12/31/21	-259	-1,681	-1,427	-1,402	-1,424	-1,405	-1,352	-1,377	-1,391	-1,405	-6,193	-13,123
2. Extension and modification of residential energy efficient property credit (sunset 12/31/31)	ema DOE	-46	-514	-1,216	-3,012	-3,098	-3,188	-3,283	-3,378	-3,459	-3,563	-7,886	-24,756
3. Energy efficient commercial buildings deduction (sunset 12/31/31)	tyba 12/31/21 & ppisa 12/31/21 ityeasd	-18	-72	-70	-68	-67	-66	-65	-66	-67	-69	-295	-626
4. Extension, increase, and modifications of new energy efficient home credit (sunset 12/31/31)	duaa 12/31/21	-132	-233	-258	-271	-289	-307	-321	-320	-305	-289	-1,182	-2,724
5. Modifications to income exclusion for conservation subsidies	ara 12/31/18	-6	-2	-2	-3	-4	-5	-6	-6	-7	-7	-17	-48

JA737

Case: 24-1820 Document: 28-3 Page: 332 Date Filed: 07/12/2024

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
6. Credit for qualified wildfire mitigation expenditures.....	epoia DOE ityeasd	-12	-28	-31	-36	-42	-44	-46	-48	-49	-50	-149	-387
Total of Part 3 - Green Energy and Efficiency Incentives for Individuals…..		**-473**	**-2,530**	**-3,004**	**-4,792**	**-4,924**	**-5,015**	**-5,073**	**-5,195**	**-5,278**	**-5,383**	**-15,722**	**-41,664**
Part 4 - Greening the Fleet and Alternative Vehicles													
1. Refundable new qualified plug-in electric drive motor vehicle credit for individuals (sunset 12/31/31) [7].....	vaa 12/31/21 & vaa 12/31/22	-96	-494	-576	-709	-832	-1,001	-1,171	-1,304	-1,447	-1,559	-2,709	-9,192
2. Credit for previously-owned qualified plug-in electric drive motor vehicles (sunset 12/31/31).....	vaa 12/31/21	-33	-104	-119	-150	-166	-183	-202	-224	-247	-269	-572	-1,696
3. Qualified commercial electric vehicles (sunset 12/31/31).....	vaa 12/31/21	-79	-171	-235	-303	-396	-516	-624	-717	-808	-914	-1,184	-4,762
4. Qualified fuel cell motor vehicles (sunset 12/31/31).....	ppisa 12/31/21	-4	-7	-8	-9	-11	-4	---	---	---	---	-40	-44
5. Alternative fuel refueling property credit (sunset 12/31/31).....	ppisa 12/31/21	-93	-404	-461	-523	-591	-666	-749	-837	-932	-1,027	-2,072	-6,283
6. Reinstatement and expansion of employer-provided fringe benefits for bicycle commuting [9].....	tyba 12/31/21	-20	-21	-23	-24	-16	-16	-18	-18	-19	-19	-103	-194
7. Credit for certain new electric bicycles (sunset 12/31/25)....	ppisa 12/21/21 ityeasd	-254	-683	-889	-1,157	-1,126	-8	-7	-6	-6	-4	-4,108	-4,139
Total of Part 4 - Greening the Fleet and Alternative Vehicles…..		**-579**	**-1,884**	**-2,311**	**-2,875**	**-3,138**	**-2,394**	**-2,771**	**-3,106**	**-3,459**	**-3,792**	**-10,788**	**-26,310**
Part 5 - Investment in the Green Workforce													
1. Extension of the advanced energy project credit [7][10].....	1/1/22	-1,476	-2,053	-1,184	-787	-796	-528	-380	-240	-169	-36	-6,296	-7,649
2. Labor costs of installing mechanical insulation property (sunset 12/31/25).....	apoia 12/31/21 ityeasd	-371	-745	-939	-1,099	-813	-532	-480	-428	-326	-207	-3,967	-5,940
3. Advanced manufacturing investment credit (sunset 12/31/25) [7].....	[11]	-1,501	-2,706	-2,931	-2,842	-913	115	130	145	151	157	-10,895	-10,197
4. Advanced manufacturing production credit (sunset 12/31/29) [7].....	cpasa 12/31/21	-214	-336	-348	-372	-401	-353	-256	-151	-40	---	-1,672	-2,472
Total of Part 5 - Investment in the Green Workforce…..		**-3,562**	**-5,840**	**-5,402**	**-5,100**	**-2,923**	**-1,298**	**-986**	**-674**	**-384**	**-86**	**-22,830**	**-26,258**
Part 6 - Qualified Environmental Justice Credit (sunset 12/31/31) [7][10]…..	**1/1/22**	**---**	**-400**	**-700**	**-800**	**-900**	**-1,000**	**-1,000**	**-1,000**	**-1,000**	**-1,000**	**-2,800**	**-7,800**
Part 7 - Reinstatement of Superfund…..	**7/1/22**	**290**	**1,229**	**1,280**	**1,323**	**1,357**	**1,390**	**1,424**	**1,459**	**1,494**	**1,530**	**5,479**	**12,776**
Part 8 - Incentives for Clean Electricity and Clean Transportation													
1. Clean electricity production credit [7].....	[12]	---	---	---	---	---	---	-19	-546	-1,878	-3,558	---	-6,002
2. Clean electricity investment credit [7].....	[12]	---	---	---	---	---	-723	-1,082	-8,774	-13,127	-13,519	---	-37,225
3. Increase in clean electricity investment credit for facilities placed in service in connection with low-income communities.....	1/1/27	*Estimate Included in Item F.8.2. Above*											
4. Cost recovery for qualified facilities, qualified property, and grid improvement property.....	fappisa 12/31/26	---	---	---	---	---	-26	-83	-134	-171	-211	---	-624
5. Clean fuel production credit [7].....	tfpa 12/31/26	---	---	---	---	---	-1,499	-2,104	-2,204	-2,320	-1,590	---	-9,716
Total of Part 8 - Incentives for Clean Electricity and Clean Transportation…..		**---**	**---**	**---**	**---**	**---**	**-2,248**	**-3,288**	**-11,659**	**-17,496**	**-18,878**	**---**	**-53,567**
TOTAL OF SUBTITLE F - GREEN ENERGY…..		**-10,210**	**-17,940**	**-21,456**	**-27,193**	**-30,980**	**-31,369**	**-30,819**	**-41,067**	**-49,128**	**-51,578**	**-107,782**	**-311,741**

JA738

Case: 24-1820 Document: 28-3 Page: 333 Date Filed: 07/12/2024

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
SUBTITLE G - SOCIAL SAFETY NET													
Part 1 - Child Tax Credit: Extend and modify ARP modifications to CTC, income lookback for phase out, expanded safe harbor, fully advanced credit with MAGI limit, no child SSN requirement (sunset 12/31/22); no child SSN requirement, full refundability of CTC (not the $500 credit) (taxable years beginning after 12/31/22) [7]	**tyba 12/31/21**	**-101,390**	**-28,936**	**-12,236**	**-11,714**	**-12,669**	**-3,604**	**-3,527**	**-3,503**	**-3,515**	**-3,551**	**-166,945**	**-184,646**
Part 2 - Earned Income Tax Credit													
1. Certain improvements to the earned income tax credit extended through 2022 [7]	tyba 12/31/21	-578	-12,693	---	---	---	---	---	---	---	---	-13,271	-13,271
2. Funds for administration of earned income tax credits in the territories [7]	pmf cyba 12/31/21	---	-5	-5	-5	-5	-5	-5	-5	-5	-5	-20	-45
Total of Part 2 - Earned Income Tax Credit		**-578**	**-12,698**	**-5**	**-5**	**-5**	**-5**	**-5**	**-5**	**-5**	**-5**	**-13,291**	**-13,316**
Part 3 - Expanding Access to Health Coverage and Lowering Costs													
1. Improve affordability and reduce premium costs of health insurance for consumers (sunset 12/31/25)	tyba 12/31/21	*Estimate to be Provided by the Congressional Budget Office*											
2. Modification of employer sponsored coverage affordability test in health insurance premium tax credit (sunset 12/31/25)	tyba 12/31/21	*Estimate to be Provided by the Congressional Budget Office*											
3. Treatment of lump-sum Social Security benefits in determining household income	tyba 12/31/21	*Estimate to be Provided by the Congressional Budget Office*											
4. Temporary expansion of health insurance premium tax credits for certain low-income populations (sunset 12/31/25) [13]	tyba 12/31/21	*Estimate to be Provided by the Congressional Budget Office*											
5. Special rule for individuals receiving unemployment compensation (sunset 12/31/22)	tyba 12/31/21	*Estimate to be Provided by the Congressional Budget Office*											
6. Permanent credit for health insurance costs [7]	cmba 12/31/21	-8	-18	-19	-20	-31	-44	-47	-49	-52	-56	-96	-344
7. Exclusion of certain dependent income for purposes of premium tax credit (sunset 12/31/26)	tyba 12/31/22	*Estimate to be Provided by the Congressional Budget Office*											
8. Requirements with respect to cost-sharing for certain insulin products	pybo/a 1/1/23	*Estimate to be Provided by the Congressional Budget Office*											
9. Oversight of pharmacy benefit manager services	pybo/a 1/1/23	*Estimate to be Provided by the Congressional Budget Office*											
Total of Part 3 - Expanding Access to Health Coverage and Lowering Costs		**-8**	**-18**	**-19**	**-20**	**-31**	**-44**	**-47**	**-49**	**-52**	**-56**	**-96**	**-344**
Part 4 - Pathway to Practice Training Programs - Establishing rural and underserved pathway to practice training programs for post-baccalaureate students, medical students, and medical residents [7]	**tyba DOE**	**---**	**---**	**-74**	**-165**	**-262**	**-387**	**-589**	**-844**	**-1,136**	**-1,420**	**-500**	**-4,877**

JA739

Case: 24-1820 Document: 28-3 Page: 334 Date Filed: 07/12/2024

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
Part 5 - Higher Education													
1. Credit for public university research infrastructure	qccma 12/31/21	-33	-37	-36	-36	-26	-9	---	---	---	---	-168	-177
2. Treatment of Federal Pell Grants for income tax purposes (sunset 12/31/25) [7]	tyba 12/31/21	-6	-229	-225	-215	-205	---	---	---	---	---	-880	-880
3. Repeal of denial of American Opportunity Tax Credit on basis of felony drug conviction [7]	tyba 12/31/21	-3	-21	-21	-20	-20	-20	-20	-19	-18	-18	-85	-180
Total of Part 5- Higher Education		**-42**	**-287**	**-282**	**-271**	**-251**	**-29**	**-20**	**-19**	**-18**	**-18**	**-1,133**	**-1,237**
Part 6 - Limit Itemized Deductions for State and Local Taxes to $80,000	**tyba 12/31/20**	**-52,133**	**-51,827**	**-54,028**	**-56,277**	**-15,733**	**44,182**	**40,129**	**41,607**	**43,198**	**75,677**	**-229,998**	**14,795**
TOTAL OF SUBTITLE G - SOCIAL SAFETY NET		**-154,151**	**-93,766**	**-66,644**	**-68,452**	**-28,951**	**40,113**	**35,941**	**37,187**	**38,472**	**70,627**	**-411,963**	**-189,625**
SUBTITLE H - RESPONSIBLY FUNDING OUR PRIORITIES													
Part 1 - Corporate and International Tax Reforms													
A. Corporate Provisions													
1. Corporate alternative minimum tax	tyba 12/31/22	4,481	55,753	49,165	32,588	24,695	22,747	25,789	30,535	34,969	38,189	166,682	318,911
2. Excise tax on repurchase of corporate stock	rosa 12/31/21	8,212	11,782	12,011	12,343	13,149	13,632	13,569	13,208	13,051	13,267	57,497	124,226
B. Limitations on Deduction for Interest Expense	tyba 12/31/22	---	1,520	3,123	3,285	3,254	3,173	3,279	3,398	3,435	3,430	11,182	27,896
C. Outbound International Provisions													
1. Modifications to deduction for foreign-derived intangible income and global intangible low-taxed income	[14]	---	12,597	26,422	28,687	20,624	11,481	11,432	11,109	11,000	10,926	88,330	144,278
2. Repeal of election for 1-month deferral in determination of taxable year of specified foreign corporations	tyosfcba 11/30/22	---	3,353	3,353	[15]	---	---	---	---	---	---	6,706	6,706
3. Modifications of foreign tax credit rules applicable to certain taxpayers receiving specific economic benefits	apoaa 12/31/21	217	438	469	619	802	769	903	941	772	791	2,545	6,721
4. Modifications to foreign tax credit limitations	[16]	-18	698	1,621	2,010	2,006	1,597	1,207	966	850	1,064	6,317	12,000
5. Foreign oil and gas extraction income and foreign oil related income to include oil shale and tar sands	tyba 12/31/21	*Estimate Included in Item H.1.C.6. Below*											
6. Modifications to inclusion of global intangible low-taxed income	[17]	150	1,273	4,102	6,175	5,997	5,896	6,837	8,022	8,838	9,691	17,697	56,980
7. Modifications to determination of deemed paid credit for taxes properly attributable to tested income	[18]	---	-1,514	-3,155	-3,250	-3,057	-3,022	-3,194	-3,350	-3,397	-3,255	-10,976	-27,194
8. Deduction for foreign source portion of dividends limited to controlled foreign corporations, etc	[19]	21	42	44	45	46	48	49	51	52	54	198	451
9. Limitation on foreign base company sales and services income	[20]	9	814	1,754	1,913	1,534	1,144	1,162	1,190	1,232	1,287	6,025	12,041
D. Inbound International Provisions													
1. Modifications to base erosion and anti-abuse tax	tyba 12/31/21	-1,633	-2,531	1,529	7,233	9,260	9,412	10,191	10,578	11,144	11,904	13,858	67,088
E. Other Business Tax Provisions													
1. Credit for clinical testing of orphan drugs limited to first use or indication	tyba 12/31/21	88	186	208	234	260	286	314	346	380	418	975	2,720
2. Modifications to treatment of certain losses	lai tyba 12/31/21 & lo/a DOE	25	165	172	179	186	193	201	209	217	226	726	1,773
3. Adjusted basis limitation for divisive reorganization	roo/a DOE	689	1,294	1,769	1,917	1,944	1,975	2,006	2,037	2,069	2,103	7,613	17,803

Case: 24-1820 Document: 28-3 Page: 335 Date Filed: 07/12/2024

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
4. Rents from prison facilities not treated as qualified income for purposes of REIT income tests	tyba 12/31/21	5	9	10	10	6	3	3	3	3	3	40	55
5. Modifications to exemption for portfolio interest	oia DOE	576	876	405	118	25	20	16	13	10	8	2,000	2,067
6. Certain partnership interest derivatives	pma 12/31/22	4	9	9	9	9	10	10	10	10	10	41	90
7. Adjustments to earnings and profits of controlled foreign corporations	[21]	150	325	375	425	475	525	575	625	675	725	1,750	4,875
8. Certain dividends from controlled foreign corporations to United States shareholders treated as extraordinary dividends	[22]	*Estimate Included in Item H.1.C.4. Above*											
9. Limitation on certain special rules for section 1202 gains	generally saeoa 9/13/21	69	470	517	572	639	698	705	710	677	661	2,267	5,718
10. Constructive sales	generally csa DOE	*Estimate Included in Item H.1.E.12. Below*											
11. Rules relating to common control	tyba 12/31/21	628	1,267	1,276	1,313	1,434	1,601	1,788	2,011	2,248	2,457	5,919	16,023
12. Modification of wash sale rules	sdata 12/31/21	3,226	4,946	2,725	1,626	1,074	804	653	587	562	559	13,597	16,762
13. Research and experimental expenditures (sunset 12/31/25)	DOE	-29,091	-39,856	-32,161	-24,133	19,284	38,009	29,958	19,853	9,269	4,851	-105,956	-4,016
Total of Part 1 - Corporate and International Tax Reforms		**-12,192**	**53,916**	**75,743**	**73,918**	**103,646**	**111,001**	**107,453**	**103,052**	**98,066**	**99,369**	**295,033**	**813,974**
Part 2 - Tax Increases for High-Income Individuals													
1. Application of net investment income tax to trade or business income of certain high income individuals	tyba 12/31/21	12,742	19,543	21,734	24,050	25,861	27,966	28,997	29,675	30,439	31,156	103,930	252,163
2. Limitations on excess business losses of noncorporate taxpayers made permanent, with carryforward modification	tyba 12/31/20	3,127	2,046	2,123	2,204	2,288	21,665	31,221	30,130	31,909	33,563	11,788	160,276
3. Surcharge on high income individuals, estates, and trusts (initial surtax on AGI of 5% in excess of $10,000,000 and additional surtax of 3% on AGI in excess of $25,000,000)	tyba 12/31/21	40,035	-18,667	22,215	23,436	24,332	24,223	25,465	27,540	28,779	30,413	91,350	227,771
Total of Part 2 - Tax Increases for High-Income Individuals		**55,904**	**2,922**	**46,072**	**49,690**	**52,481**	**73,854**	**85,683**	**87,345**	**91,127**	**95,132**	**207,068**	**640,210**
Part 3 - Modifications of Rules Relating to Retirement Plans													
A. Limitations on High-Income Taxpayers with Large Retirement Account Balances													
1. Contribution limit for individual retirement plans of high-income taxpayers with large account balances	tyba 12/31/28 & pyba 12/31/28	*Estimate Included in Item H.3.A.2. Below*											
2. Increase in minimum required distributions for high-income taxpayers with large retirement account balances	tyba 12/31/28 & pyba 12/31/28	---	---	---	---	---	---	---	3,269	2,713	1,362	---	7,344
B. Other Provisions Relating to Individual Retirement Plans													
1. Tax treatment of rollovers to Roth IRAs and accounts	[23]	73	151	177	195	211	227	239	251	322	878	808	2,724
2. Statute of limitations with respect to IRA noncompliance	[24]	[15]	1	1	1	1	1	1	1	1	1	3	7
3. IRA owners treated as disqualified persons for purposes of prohibited transaction rules	toa 12/31/21	---	1	1	1	1	1	2	2	2	2	5	13
Total of Part 3 - Modifications of Rules Relating to Retirement Plans		**73**	**153**	**179**	**196**	**213**	**229**	**241**	**3,522**	**3,038**	**2,242**	**815**	**10,087**

JA741

Case: 24-1820 Document: 28-3 Page: 336 Date Filed: 07/12/2024

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
Part 4 - Funding the Internal Revenue Service and Improving Taxpayer Compliance													
1. Enhancement of Internal Revenue Service resources	DOE	*Estimate to be Provided by the Congressional Budget Office*											
2. Application of backup withholding with respect to third party network transactions	cyba 12/31/21	-2	-1	[4]	[4]	[4]	[4]	[4]	[4]	[4]	[4]	-3	-4
3. Modification of procedural requirements relating to assessment of penalties	[25]	201	221	113	116	119	122	125	128	132	135	771	1,414
Total of Part 4 - Funding the Internal Revenue Service and Improving Taxpayer Compliance		**199**	**220**	**113**	**116**	**119**	**122**	**125**	**128**	**132**	**135**	**768**	**1,410**
Part 5 - Other Provisions													
1. Modifications to limitation on deduction of excessive employee remuneration	tyba 12/31/21	315	639	656	674	683	692	868	881	893	905	2,966	7,205
2. Extension of tax to fund Black Lung Disability Trust Fund [26]	sa 12/31/21	101	137	135	131	32	---	---	---	---	---	536	536
3. Prohibited transactions relating to holding DISC or FSC in individual retirement account	saoiaoho/a 12/31/21	39	95	126	157	187	217	249	277	292	301	605	1,940
4. Clarification of treatment of DISC gain and distributions of certain foreign shareholders	goda 12/31/21	41	86	92	95	96	97	99	101	103	106	410	915
5. Treatment of certain qualified sound recording productions [27]	pci tyea DOE	-310	-59	6	43	112	86	43	21	11	12	-208	-35
6. Payment to certain individuals who dye fuel	[28]	[4]	[4]	[4]	[4]	[4]	[4]	[4]	[4]	[4]	[4]	-2	-4
7. Treatment of financial guaranty insurance companies as qualifying insurance corporations under passive foreign investment company rules	tyba 12/31/17 & rma DOE	[4]	-2	-4	-5	-8	-9	-12	-14	-14	-14	-18	-81
8. Extension of period of limitation for certain legally married couples	DOE	-33	-22	---	---	---	---	---	---	---	---	-55	-55
9. Allow an above-the-line deduction of up to $250 in union dues paid (sunset 12/31/25)	tyba 12/31/21	-66	-442	-442	-443	-377	---	---	---	---	---	-1,770	-1,770
10. Temporary increase in employer-provided child care credit (sunset 12/31/25)	tyba 12/31/21	-30	-41	-42	-43	-11	---	---	---	---	---	-166	-166
11. Payroll credit for compensation of local news journalists (sunset 12/31/26)	cqba DOE	-207	-366	-310	-308	-320	-162	---	---	---	---	-1,511	-1,674
12. Allow an above-the-line deduction of up to $250 for employee uniforms (sunset 12/31/24)	tyba 12/31/21	-111	-742	-756	-650	---	---	---	---	---	---	-2,259	-2,259
13. Expenses in contingency fee cases	apiori tyba DOE	-172	-659	-532	-390	-231	-101	-105	-101	-95	-66	-1,985	-2,453
14. Increase in research credit against payroll tax for small businesses	tyba 12/31/21	-51	-81	-85	-89	-94	-98	-102	-107	-111	-113	-401	-932
15. Imposition of tax on nicotine	[29]	180	1129	1173	1126	1028	940	865	792	720	654	4,635	8,606
16. Termination of employer credit for paid family and medical leave [30]	tyba 12/31/23	---	---	101	219	168	77	44	26	7	---	489	642
Total of Part 5 - Other Provisions		**-304**	**-328**	**118**	**517**	**1,265**	**1,740**	**1,949**	**1,876**	**1,806**	**1,785**	**1,266**	**10,415**
TOTAL OF SUBTITLE H - RESPONSIBLY FUNDING OUR PRIORITIES		**43,680**	**56,883**	**122,225**	**124,437**	**157,725**	**186,945**	**195,452**	**195,923**	**194,169**	**198,663**	**504,950**	**1,476,096**

JA742

Case: 24-1820 Document: 28-3 Page: 337 Date Filed: 07/12/2024

Provision	Effective	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
SUBTITLE I - DRUG PRICING: Selected Drug Manufacturer Excise Tax Imposed During Noncompliance Periods…	**sa DOE**	*No Revenue Effect*											
NET TOTAL …		**-121,349**	**-56,406**	**31,569**	**25,519**	**94,030**	**191,839**	**197,088**	**188,781**	**180,404**	**214,550**	**-26,643**	**946,015**

Joint Committee on Taxation

NOTE: Details may not add to totals due to rounding. The date of enactment is assumed to be December 1, 2021.

Legend for "Effective" column:

apiori = amounts paid, incurred, or received in
apoia = amounts paid or incurred after
apoaa = amounts paid or accrued after
ara = amounts received after
bpisa = buildings placed in service after
cpasa = components produced and sold after
cqba = calendar quarters beginning after
csa = constructive sales after
cya = calendar years after
cyba = calendar years beginning after
da = days after
DOE = date of enactment
duaa = dwelling units acquired after
ema = expenditures made after
epasa = electricity produced and sold after
epoia = expenditures paid or incurred after
fappisa = facilities and property placed in service after
foetcowba = facilities or equipment the construction of which begins after
fpisa = facilities placed in service after
fsoua = fuel sold or used after
ftcowba = facilities the construction of which begins after
goda = gains or distributions after
itybasd = in taxable years beginning after such date
ityeasd = in taxable years ending after such date
lai = losses arising in
lii = losses incurred in
lo/a = liquidations on or after
oia = obligations issued after
oii = obligations issued in
pa = periods after
pci = productions commencing in
pmf = payments made for
pma = payments made after
ppisa = property placed in service after
ptcowba = property the construction of which begins after
pybo/a = plan years beginning on or after
roo/a = reorganizations occurring on or after
rosa = repurchases of stock after
rma = reports made after
qccma = qualified cash contributions made after
qsgbpa = qualified second generation biofuel production after
sa = sales after
saeoa = sales and exchanges only after
saoiaoho/a = stock and other interests acquired or held on or after
sdata = sales, dispositions, and terminations after
tfpa = transportation fuel produced after
toa = transactions occurring after
too/a = transfers occurring on or after
tyba = taxable years beginning after
tyea = taxable years ending after
tyosfcba = taxable years of specified foreign corporations beginning after
vaa = vehicles acquired after

[1] Effective for buildings some portion of which, or of the land on which the building is located, is financed by an obligation which is described in section 42(h)(4)(A) and which is part of an issue the issue date of which is after December 31, 2021.

[2] Effective for allocations of housing credit dollar amount after December 31, 2021, and for buildings that are described in section 42(h)(4)(B) taking into account only obligations that are part of an issue the issue date of which is after December 31, 2021.

[3] The amendments made by subsections (a) and (c) shall apply to agreements entered into or amended after the date of the enactment. The amendments made by subsection (b) shall apply to agreements among the owners of the project (including partners, members, and their affiliated organizations) and persons described in section 42(i)(7)(A) of the Internal Revenue Code of 1986 entered in of the Internal Revenue Code of 1986 entered into before, on, or after the date of the enactment.

[4] Loss of less than $500,000.

[5] Applies to taxable years beginning after the date of the enactment of this Act, and in the case of a qualified corporation that is foreign corporation, to taxable years beginning after the date of enactment and to taxable years of United States shareholders in which or with which taxable years of foreign corporations end. The credit is not available for taxable years beginning after December 31, 2031.

[6] Effective as if included in sec. 1005 of the American Rescue Plan Act of 2021 (Public Law 117-2).

[7] Estimate contains the following outlay effects:

	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
Credit for electricity produced from certain renewable resources (sunset /12/31/26)……	87	281	498	825	1,375	2,008	2,712	3,489	4,229	5,064	3,066	20,568
Extension and modification of energy credit (sunset 12/31/26)……	369	663	751	1,274	2,854	3,627	3,642	3,741	3,933	4,144	5,911	24,999
Investment credit for electric transmission property (sunset 12/31/31)……	---	---	---	328	504	504	504	832	353	---	832	3,024

[Footnotes for JCX-46-21 continue on the following pages]

JA743

Case: 24-1820 Document: 28-3 Page: 338 Date Filed: 07/12/2024

Footnotes for JCX-46-21 continued:

[7] Estimate contains the following outlay effects (continued):	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
Zero-emission nuclear power production credit (sunset 12/31/27)	2,104	1,396	1,562	1,692	1,781	1,842	651	---	---	---	8,534	11,028
Credit for production of clean hydrogen	34	87	143	220	311	409	518	640	684	677	795	3,723
Refundable new qualified plug-in electric drive motor vehicle credit for individuals (sunset 12/31/31)	55	62	70	82	98	117	130	145	159	159	367	1,077
Extension of the advanced energy project credit	708	986	569	378	382	253	183	115	81	17	3,022	3,672
Advanced manufacturing investment credit (sunset 12/31/25)	627	1,130	1,223	1,186	1,116	349	---	---	---	---	5,282	5,632
Advanced manufacturing production tax credit (sunset 12/31/29)	93	147	152	162	175	154	112	66	17	---	730	1,079
Qualified environmental justice credit (sunset 12/31/31)	---	380	665	760	855	950	950	950	950	950	2,660	7,410
Clean electricity production credit	---	---	---	---	---	---	9	262	901	1,708	---	2,881
Clean electricity investment credit	---	---	---	---	---	347	519	4,212	6,301	6,489	---	17,868
Clean fuel production credit	---	---	---	---	---	720	1,010	1,058	1,113	763	---	4,664
Child tax credit	78,647	21,355	12,236	11,714	12,669	3,604	3,527	3,503	3,515	3,551	136,621	154,322
Certain improvements to the earned income tax credit extended through 2022	---	10,381	---	---	---	---	---	---	---	---	10,381	10,381
Funds for administration of earned income tax credits in the territories	---	5	5	5	5	5	5	5	5	5	20	45
Permanent credit for health insurance costs	5	7	8	8	15	18	19	20	21	22	43	143
Federal Pell Grants excluded from gross income	---	167	159	153	150	---	---	---	---	---	629	629
Repeal of denial of American Opportunity Tax Credit on basis of felony drug conviction	---	6	6	6	6	6	6	5	5	5	23	50
Establishing rural and underserved pathway to practice training programs for post-baccalaureate students, medical students, and medical residents [31]	---	---	37	82	131	205	370	614	899	1,176	250	3,514

[8] Effective for hydrogen produced after December 31, 2021, at facilities for which construction commenced on or before December 31, 2028; for facilities the construction of which begins after December 31, 2021, for electricity produced after December 31, 2021, for property placed in service after December 31, 2021, and, for any property the construction of which begins prior to January 1, 2022, only to the extent of the basis thereof attributable to the construction, reconstruction, or erection after December 31, 2026.

[9] Estimate includes the following budget effects:	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
Total Revenue Effect	-20	-21	-23	-24	-16	-16	-18	-18	-19	-19	-103	-194
On-budget effects	-12	-13	-14	-15	-9	-10	-10	-11	-11	-12	-63	-117
Off-budget effects	-8	-8	-9	-9	-6	-7	-7	-7	-8	-8	-40	-77

[10] Annual base allocation amounts end 2031, unused amounts may be reallocated through 2036.

[11] Effective for property placed in service after December 31, 2021, and, for any property the construction of which begins prior to January 1, 2022, only to the extent of the basis thereof attributable to the construction, reconstruction, or erection after December 31, 2021.

[12] Effective for property placed in service after December 31, 2026, and, for any property the construction of which begins prior to January 1, 2027, only to the extent of the basis thereof attributable to the construction, reconstruction, or erection after December 31, 2026.

[13] For purposes of this subsection, the term 'termination date' means the later of January 1, 2025, or the date on which the Secretary of Health and Human Services makes a written certification to the Secretary that the Secretary of Health and Human Services has fully implemented the program described in section 1948.

[14] Generally applies to tyba 12/31/22, except that certain other modifications apply to taxable years beginning after the date of enactment.

[15] Gain of less than $500,000.

[16] Generally effective for taxable years beginning after December 31, 2022, with the following exceptions: changes with respect to foreign tax credit carryback or carryover are effective for taxes paid or accrued in taxable years beginning after December 31, 2022; changes to the treatment of certain asset dispositions are generally effective for transactions after the date of enactment; changes to elections of claims or deductions are effective for taxes paid or accrued for taxable years beginning after December 31, 2021; changes related to redeterminations of foreign taxes are effective for changes that occur 60 days or more after DOE; and changes to the special limitations period are effective for taxes paid, accrued or deemed paid in in taxable years beginning after December 31, 2021.

[Footnotes for JCX-46-21 continue on the following page]

JA744

Case: 24-1820 Document: 28-3 Page: 339 Date Filed: 07/12/2024

Footnotes for JCX-46-21 continued:

[17] Generally applies to taxable years of foreign corporations beginning after December 31, 2022, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end, except that changes to regulatory authority and coordination with other provisions apply to taxable years of foreign corporations beginning after date of enactment, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end.

[18] Generally applies to taxable years of foreign corporations beginning after December 31, 2021 2022, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end, except that changes to the application of the foreign tax credit limitation to amounts included under section 78 and the disallowance of foreign tax credit and deduction with respect to distributions of previously taxed global intangible low-taxed income apply to taxable years of foreign corporations beginning after date of enactment, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end.

[19] Generally applies to distributions made after date of enactment, exception that modifications related to the determination of status as controlled foreign corporation apply to taxable years of foreign corporations beginning after the date of the enactment, and taxable years of United States persons in which or with which such taxable years of foreign corporations end.

[20] Applies to taxable years of foreign corporations beginning after December 31, 2021, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end.

[21] Applies to taxable years of foreign corporations ending after the date of enactment, and to taxable years of United States shareholders in which or with which such taxable years of foreign corporations end.

[22] Applies to dividends paid (or amounts treated as dividends) after the date of enactment.

[23] The amendments made by subsection (a) shall apply to distributions, transfers, and contributions made after December 31, 2021. The amendments made by subsection (b) shall apply to distributions, transfers, and contributions made in taxable years beginning after December 31, 2031.

[24] Applicable for taxes with respect to which the 3-year period under section 6501(a) of the Internal Revenue Code of 1986 (without regard to the amendment made by this section) ends after December 31, 2021.

[25] Repeal of Internal Revenue Code section 6751(b) is effective as if included in section 3306 of the Internal Revenue Service Restructuring and Reform Act of 1998. Quarterly certifications of compliance with procedural requirements apply to notices of penalty issued after date of enactment.

[26] The temporary increase in the amount of tax on coal terminates for sales after December 31, 2025.

[27] Sunsets 12/31/25 (section 181) and 12/31/26 (section 168(k)).

[28] Effective for eligible indelibly dyed diesel fuel or kerosene removed on or after the date which is 180 days after the date of enactment.

[29] The amendments made by this section shall apply to articles removed in calendar quarters beginning after the date which is 180 days after the date of enactment.

[30] Estimate includes the following budget effects:

	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2022-26	2022-31
Total Revenue Effect	---	---	101	219	168	77	44	26	7	---	489	642
On-budget effects	---	---	107	227	171	77	44	26	7	---	505	659
Off-budget effects	---	---	-6	-8	-2	---	---	---	---	---	-17	-17

[31] Outlays arising from Medicare funding of residency positions are provided by the Congressional Budget Office.

JA745

Case: 24-1820 Document: 28-3 Page: 340 Date Filed: 07/12/2024

Exhibit F

Congressional Budget Office
Nonpartisan Analysis for the U.S. Congress

How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act

February 2023

JA747

Case: 24-1820 Document: 28-3 Page: 342 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 343 Date Filed: 07/12/2024

JA748

Prescription Drug Provisions Are Part of the 2022 Reconciliation Act

The act, which became Public Law 117-169 in August 2022, contains roughly 150 provisions, including ones that:

- Affect prescription drug prices and coverage under Medicare,
- Expand health insurance subsidies established by the Affordable Care Act,
- Establish a new alternative minimum tax on corporations,
- Provide additional funding for the Internal Revenue Service, and
- Create subsidies for renewable energy.

The Congressional Budget Office estimated that the provisions related to prescription drugs would reduce the deficit by $237 billion from 2022 to 2031. Three key policies discussed in this document are responsible for $129 billion of that reduction.

The rest of the deficit reduction largely results from delaying a rule (commonly known as the safe harbor rule) to restrict the ability of manufacturers and insurers to negotiate rebates for prescription drugs. The estimates in this document reflect that delay.

For additional information on the estimate for the 2022 Reconciliation Act, see Congressional Budget Office, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 (September 7, 2022), www.cbo.gov/publication/58455. Overall, CBO estimated that the law would decrease the deficit by $58 billion over the 2022–2031 period, excluding any additional revenue resulting from an increased appropriation to the Internal Revenue Service. For additional information on the safe harbor rule, see Congressional Budget Office, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections" (supplemental material for *Updated Budget Projections: 2019 to 2029*, May 2019), www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

Key Prescription Drug Provisions Establish Price Negotiation and Inflation Rebates—and Redesign Part D Benefits

Medicare covers prescription drugs under two parts of the program. Part B covers drugs administered by a physician or other health care professional—primarily injectable and infused drugs—in addition to doctors' visits, outpatient hospital services, and related care. Part D generally covers prescription drugs purchased at a retail pharmacy.

Under the act, the Secretary of Health and Human Services (HHS) will negotiate prices for certain prescription drugs covered under Medicare Part B and Part D.

Manufacturers of drugs covered under Medicare Part B and Part D must pay rebates to Medicare if the prices of brand-name drugs without generic or biosimilar competition exceed an inflation-adjusted benchmark.

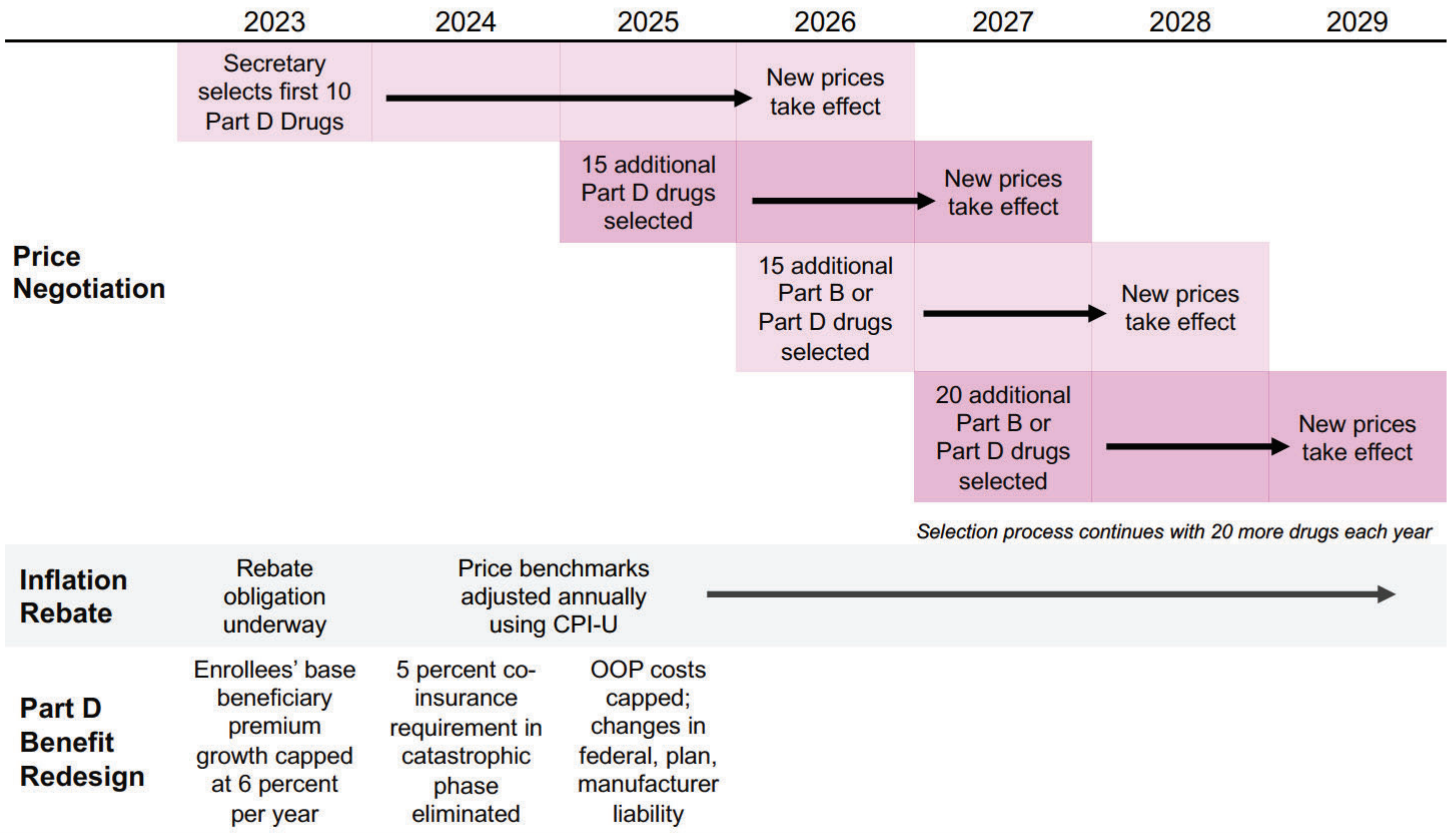
The law redesigns the Medicare Part D benefit in numerous ways, including to:

- Cap enrollees' annual out-of-pocket costs and limit their premium increases,
- Reduce Medicare's share of costs beyond the out-of-pocket cap, and
- Require manufacturers to provide new mandatory price discounts.

JA749

Case: 24-1820 Document: 28-3 Page: 344 Date Filed: 07/12/2024

The Act's Key Prescription Drug Provisions Will Be Phased In Over Time



To be selected for negotiation, a Part D drug must be among the 50 top-selling products without generic or biosimilar competition in Part D. When Part B drugs become eligible in 2026, those selected must be among the top 50 such drugs in Part B. Selected drugs must meet other criteria as well.

A manufacturer's rebate obligation is based on a drug's price in 2021 or its launch year, if launched after 2021.

The cap on OOP costs, set at $2,000 in 2025, increases annually at the rate of growth in Part D costs per capita.

CPI-U = consumer price index for all urban consumers; OOP = out-of-pocket. The inflation rebate obligation for Part D began October 1, 2022; for Part B, it began January 1, 2023.

Case: 24-1820 Document: 28-3 Page: 345 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 346 Date Filed: 07/12/2024

JA751

Three Key Policies Discussed Here Will Reduce the Budget Deficit in 2031 by an Estimated $31 Billion

Price Negotiation: CBO estimated that price negotiation will lower average drug prices paid by Medicare and will reduce the budget deficit by $25 billion in 2031: Part D spending will be $14 billion lower than it would have been, Part B drug spending will be $9 billion lower, and other federal spending will be $1 billion lower on net.

Inflation Rebates: Rebate payments, lower drug prices, and lower health insurance premiums in the commercial market will lower federal spending and increase federal revenues, according to CBO's estimates. Higher prices in Medicaid are expected to offset some of that lowered spending. CBO estimated that, overall, the inflation rebate policy will reduce the federal budget deficit by $8 billion in 2031.

Part D Redesign: Increased federal subsidies, premium stabilization, and increased use of drugs will put upward pressure on the deficit. Other aspects of the benefit redesign will put downward pressure on the deficit. On net, the deficit is estimated to rise by $2 billion in 2031 because of the redesign.

Components do not sum to totals because of rounding. To estimate the incremental effects of each of the key drug provisions discussed in this document, CBO analyzed the three policies in the following sequence: (1) negotiation, (2) inflation rebate, and (3) Part D redesign. CBO estimated the inflation rebate effect relative to a policy scenario that includes negotiation, and estimated the Part D redesign effect relative to a scenario that includes both negotiation and the inflation rebate. All those provisions were estimated relative to a policy scenario that includes the effects of delaying the safe harbor rule.

How the Price Negotiation Provisions Will Affect Medicare's Prices and the Deficit

Case: 24-1820 Document: 28-3 Page: 347 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 348 Date Filed: 07/12/2024

JA753

Before the Reconciliation Act, Drug Prices Were Determined by Statutory Formula in Part B and Private Negotiations in Part D

Prices for drugs have been determined through different mechanisms under Medicare Parts B and D:

- In Part B, prices were determined by a statutory formula. In most cases, Medicare pays providers a drug's average sales price (ASP) plus 6 percent.
- In Part D, prices were determined through negotiations between manufacturers and insurers or their pharmacy benefit managers.

The Secretary was prohibited from interfering or participating in pricing or formulary negotiations between manufacturers and drug plans that deliver the Part D benefit. In CBO's assessment, removing that prohibition without providing the Secretary with additional tools or leverage would not have significantly reduced drug prices or federal spending.

ASP is defined in the Medicare Part B program as the manufacturer's average price paid by all nonfederal purchasers in the United States. It includes all volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program). As described here, the Part B payment formula does not reflect the effects of sequestration arising from the Budget Control Act of 2011, which lowers the effective payment rate to ASP plus 4.3 percent.

For a discussion of the effects of drug price negotiation in Medicare, see Congressional Budget Office, letter to the Honorable Chuck Grassley on negotiation over drug prices in Medicare (May 17, 2019), www.cbo.gov/publication/55270.

The Reconciliation Act Requires the Secretary to Select Part B and Part D Drugs for Price Negotiation

The Secretary must select drugs with the largest expenditures in Medicare Part B or Part D according to the following schedule:

- 10 from Part D in 2023,
- 15 from Part D in 2025,
- 15 from either Part B or Part D (or from both) in 2026, and
- 20 from either Part B or Part D (or from both) in 2027 and later.

Selected drugs must have been on the market for at least:

- 7 years for small-molecule drugs (which are chemically synthesized drugs), or
- 11 years for biologics (which are drugs produced from living organisms).

Drugs cannot be selected if they face competition from one or more approved generic equivalents or biosimilars or if they are not among the 50 drugs with the largest expenditures in Medicare Part B or Part D.

Certain categories of drugs are excluded from selection for price negotiation, including all plasma-derived products, certain orphan drugs, and certain drugs that account for a small share of Medicare spending but a large share of the manufacturers' Medicare revenues. Total expenditures on a drug include spending by all payers and are measured at retail prices (in Part D) or at Medicare's payment rate (in Part B).

JA754

Case: 24-1820 Document: 28-3 Page: 349 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 350 Date Filed: 07/12/2024

JA755

Provisions in the Act Set an Upper Limit on Negotiated Prices

Prices determined through negotiations cannot exceed the lower of two values:

- The drug's previous average price in Medicare, or
- A specified percentage of the drug's previous nonfederal average manufacturer price.

For Part B drugs, the previous average price is the average sales price (ASP) in the prior year.

For Part D drugs, the previous average price is the average net price—that is, the price adjusted for any rebates or discounts from the manufacturer—across all Part D plans in the most recent year for which data are available.

Negotiated prices for both Part B and Part D drugs are capped at between 40 percent and 75 percent of the previous nonfederal average manufacturer price, depending on how long the drug has been on the market.

The nonfederal average manufacturer price is the average price paid to manufacturers by wholesalers for drugs distributed to nonfederal purchasers, reflecting discounts. See the glossary of terms in Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.
For a small number of drugs, negotiated prices are also constrained by a lower limit equal to 66 percent of the nonfederal average manufacturer price.

The Act Specifies Rules for the Negotiations

In negotiating the price of a drug, the Secretary must consider whether the condition the drug targets can be treated with alternative therapies, how much the drug costs to produce, the costs of research and development (including any federal support), and other factors.

Prices emerging from negotiations take effect beginning the second year after selection, except for the first cohort selected in 2023, whose prices take effect in 2026. Prices are adjusted annually based on the consumer price index for all urban consumers.

Manufacturers that do not comply with the negotiation process must either:

- Withdraw all their drug products from the Medicare and Medicaid programs, or
- Pay an excise tax initially equal to 65 percent of a product's U.S. sales and increasing to a maximum of 95 percent. The combination of that excise tax and corporate income taxes could exceed a manufacturer's profits from that product.

JA756

Case: 24-1820 Document: 28-3 Page: 351 Date Filed: 07/12/2024

CBO Expects Negotiated Prices to Be Less Than the Upper Limit

CBO expects that drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower, negotiated prices.

Based on the predictions of its bargaining model, CBO expects the Secretary's leverage in negotiations to be sufficient to attain prices below the upper limit established in the act in some cases.

CBO estimates that net prices for selected drugs will decrease by roughly 50 percent, on average, as a result of negotiation. Because those drugs are projected to account for less than one-fifth of total spending net of discounts and rebates in 2031, the estimated overall reduction in net prices in Medicare will be much smaller than 50 percent.

For information about CBO's bargaining model for negotiation, see Christopher Adams and Evan Herrnstadt, *CBO's Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act*, Working Paper 2021-01 (Congressional Budget Office, February 2021), www.cbo.gov/publication/56905.

JA757

Case: 24-1820 Document: 28-3 Page: 352 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 353 Date Filed: 07/12/2024

JA758

Negotiation is Expected to Lower Average Drug Prices and Reduce the Deficit

CBO estimated that average drug prices in 2031 will be 9 percent lower in Part B and 8 percent lower in Part D (net of rebates and discounts) because of negotiation. Lower drug prices will put downward pressure on federal spending on drugs in both programs.

With lower drug prices, Medicare enrollees, who pay a portion of drug costs, will probably use more prescription drugs, putting upward pressure on federal Medicare spending. At the same time, they will probably use fewer medical services covered under Medicare Parts A and B, lowering federal spending.

CBO estimated that negotiation will reduce the deficit by $25 billion in 2031 through the following effects:

- Part D spending will be $14 billion lower than it would have been,
- Part B drug spending will be $9 billion lower, and
- Other federal spending will be $1 billion lower on net.

Components do not sum to totals because of rounding. For a discussion of how changes in prescription drug consumption affect use of medical services and health care spending, see Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012), www.cbo.gov/publication/43741.

How the Inflation Rebate Provisions Will Affect Drug Prices and the Deficit

Case: 24-1820 Document: 28-3 Page: 354 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 355 Date Filed: 07/12/2024

JA760

Some Manufacturers Could Avoid Owing an Inflation Rebate and Maintain Net Prices by Adjusting Rebates They Pay to Part D Plans

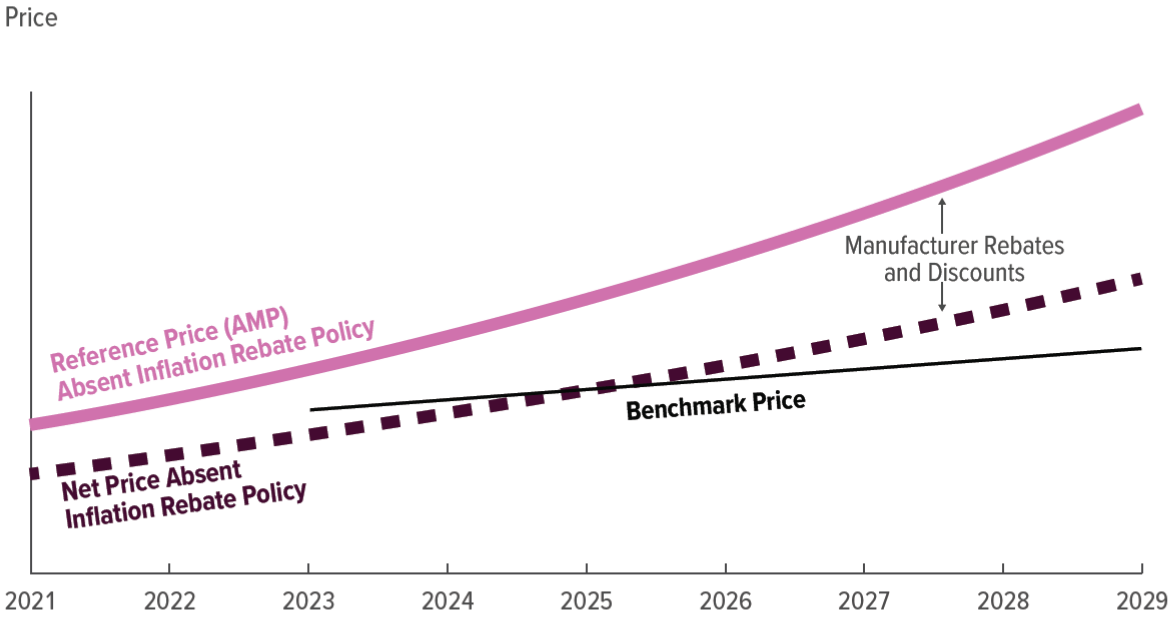
Under the act, if the reference price of a drug covered by Part B or Part D exceeds its inflation-adjusted benchmark in any given year, manufacturers must pay an inflation rebate for each unit sold to a Medicare beneficiary.

For Part D drugs, the reference price is the average manufacturer price (AMP), which is often higher than the net price because it does not reflect negotiated rebates that manufacturers pay to Part D plans. A drug's AMP is typically close to its retail price, which is the price paid to the pharmacy. For Part B drugs, the reference price is the ASP, which does reflect rebates. Because of that difference, CBO expects that manufacturers will respond to the policy for Part D drugs differently than for Part B drugs.

In Part D, the gap between the reference and net prices means that manufacturers could avoid paying the inflation rebate without reducing net prices, which determine federal insurance subsidies and manufacturers' profits. If the rebates they have been paying are large enough, manufacturers can, at least initially, reduce rebates so that the reference price remains below the benchmark without affecting net prices.

The AMP is the average price paid to a manufacturer for a drug distributed to retail pharmacies, either through wholesalers or through sales directly from manufacturers to pharmacies (not including prices for drugs dispensed primarily through the mail). Neither the AMP nor the retail price reflect rebates or other price concessions manufacturers extend to insurers.

Without the Inflation Rebate Policy, Both Reference and Net Prices of Brand-Name Part D Drugs Typically Rise Faster Than Inflation



This illustrative figure compares prices of a hypothetical drug covered by Medicare Part D without the inflation rebate policy with the benchmark price set by the policy. The benchmark is based on the drug's 2021 price and is adjusted for inflation using the CPI-U in later years.

Starting in 2023, the manufacturer owes a penalty if the reference price exceeds the benchmark.

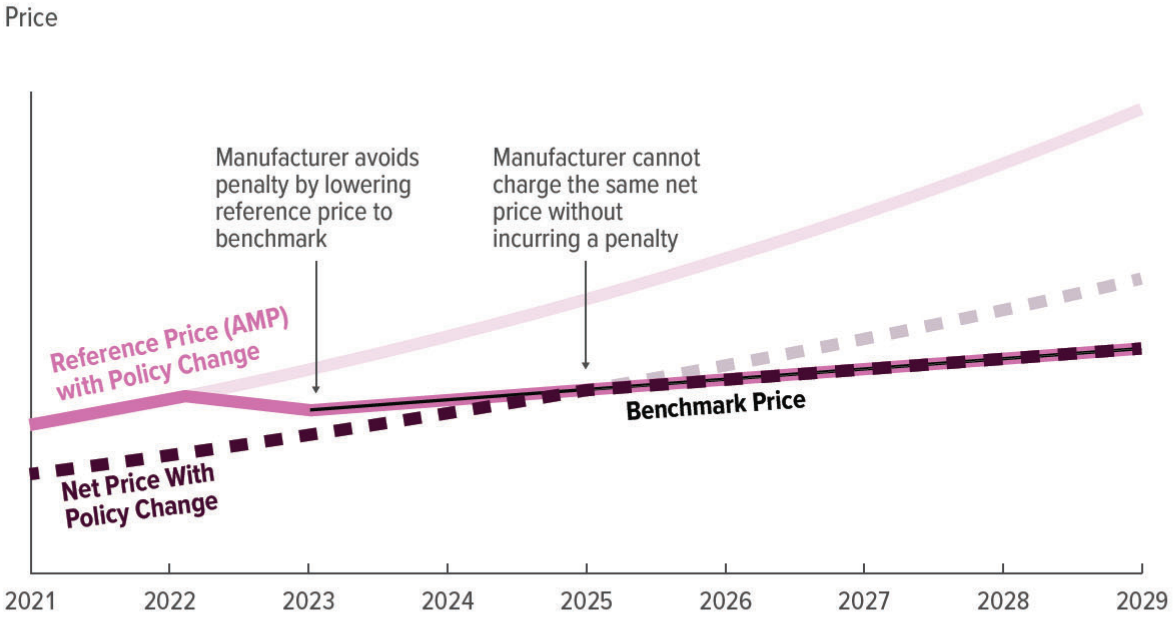
AMP = average manufacturer price; CPI-U = consumer price index for all urban consumers.

JA761

Case: 24-1820 Document: 28-3 Page: 356 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 357 Date Filed: 07/12/2024

Under Inflation Rebate Provisions, CBO Expects Lower Reference Prices for Many Drugs and Lower Net Prices for Some Drugs

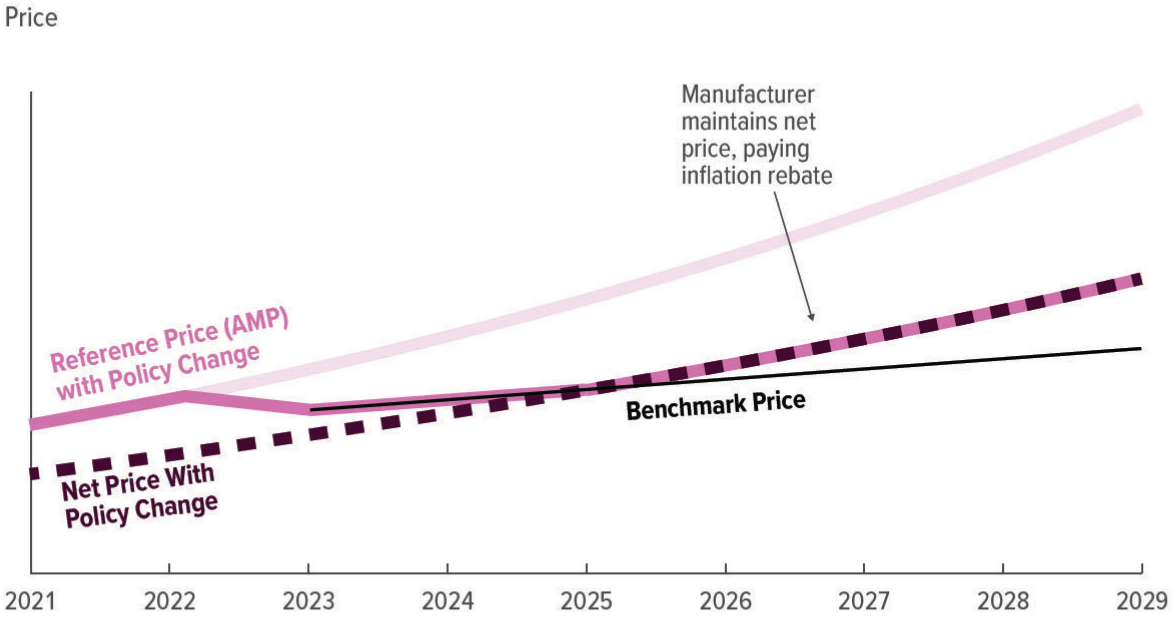


When the policy takes effect, the drug's reference price falls to avoid a penalty, but the net price is unaffected if the manufacturer can reduce rebates and discounts.

In this example, the manufacturer later chooses to constrain reference and net prices to avoid penalties. As a result, the drug's net price is lower in Medicare and commercial sectors after 2025.

The figure displays prices of a hypothetical drug to convey how a manufacturer's response to the inflation rebate policy could lead to lower net prices for a drug. The manufacturer cannot directly set the reference price of a drug but can exert considerable influence on it by changing the prices at which it sells the drug to wholesalers and pharmacies.

CBO Expects That Other Manufacturers Will Pay Inflation Rebate to Avoid Constraining Net Prices



As in the previous example, the manufacturer initially lowers the drug's reference price to the benchmark until depleting rebates and discounts.

In this case, the manufacturer then raises prices above the benchmark to avoid constraining the net price. The manufacturer then owes an inflation rebate penalty on units sold in Medicare.

The figure displays prices of a hypothetical drug to convey how a manufacturer's response to the inflation rebate policy could lead to inflation rebates paid to Medicare. The manufacturer cannot directly set the reference price of a drug but can exert considerable influence on it by changing the prices at which it sells the drug to wholesalers and pharmacies.

JA763

Case: 24-1820 Document: 28-3 Page: 358 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 359 Date Filed: 07/12/2024

JA764

CBO Projects that Retail Prices and Manufacturer Rebates Will Be Lower for Part D Drugs on the Market in 2022 and Higher for New Drugs Under the Inflation Rebate Provisions

For drugs on the market in 2022, as illustrated in the previous two charts, the inflation rebate policy tends to lower reference prices and manufacturer rebates in Part D. CBO expects that net prices will decrease for some of those drugs in both Part D and commercial markets.

For drugs brought to the market in 2023 or later, CBO expects that manufacturers will set higher initial prices to allow for slower price growth over time and that they will rebate a portion of those higher launch prices back to Part D plans to remain competitive and maintain their preferred net prices.

Changes in prices and rebates affect enrollees' spending. CBO estimates that retail prices and manufacturer rebates in Part D overall will be lower between 2023 and 2031, which will:

- Reduce payments that decrease when retail prices are lower, such as cost-sharing amounts paid by enrollees; and
- Raise payments that increase when manufacturers' rebates are lower, such as premiums paid by enrollees in Part D.

For more details, see Congressional Budget Office, *Additional Information About Prescription Drug Legislation* (August 2022), www.cbo.gov/publication/58355.

CBO Expects That the Inflation Rebate Policy Will Reduce Medicare Drug Prices

CBO estimates that average net drug prices in Part B and Part D will both be 2 percent lower in 2031 than they would have been without the inflation rebate provisions.

In Part D, that overall price decline will largely be driven by brand-name drugs whose prices have not been negotiated and that were already on the market by 2022. CBO projects that, by 2031, those drugs will account for about one-third of Part D spending.

Overall, CBO estimates that average net prices of that set of Part D drugs will be about 6 percent lower in 2031 than they would have been without the inflation rebate policy. Although the AMP for those drugs will need to be about 40 percent lower to avoid triggering inflation rebate penalties, manufacturers will offset most of those reductions by reducing rebates paid to Part D plans, the agency estimates.

JA765

Case: 24-1820 Document: 28-3 Page: 360 Date Filed: 07/12/2024

CBO Expects the Inflation Rebate Policy to Affect the Deficit Through Several Channels

Price reductions and the inflation rebate payments to the federal government are expected to reduce the budget deficit.

As with the negotiation provision, lower prices under the rebate provision tend to lower drug costs for Medicare enrollees. CBO expects Medicare enrollees to respond by increasing their use of, and spending on, prescription drugs. Spending on other Medicare-covered services will decline as a result.

CBO projects that commercial drug prices, and therefore health insurance premiums, will be lower than they would have been absent the policy. Lower premiums tend to shift some of employees' compensation from nontaxable health insurance to taxable wages, increasing tax revenues.

CBO estimates that net prices for drugs covered by Medicaid will increase because of smaller rebates under Medicaid's statutory drug rebate formula and higher prices for newly launched drugs (see next slide).

Lower drug prices and health insurance premiums tend to reduce spending on other federal health care programs such as the Federal Employees Health Benefits Program.

JA766

Case: 24-1820 Document: 28-3 Page: 361 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 362 Date Filed: 07/12/2024

JA767

CBO Projects That the Inflation Rebate Policy Will Increase Medicaid Spending

Drug manufacturers already pay rebates on prescription drugs covered by Medicaid. The rebate amount per unit in Medicaid, set by a statutory formula, is the sum of:

- The Basic Rebate (the greater of 23.1 percent of AMP or the difference between AMP and the Best Price), and
- The inflation-based rebate (the growth in AMP in excess of growth in the CPI-U).

Reductions in AMP therefore reduce both components of Medicaid's rebate. To the extent that the new *Medicare* inflation rebates reduce prices for drugs already on the market, net *Medicaid* spending will rise because the reduction in retail prices will be more than offset by reductions in *Medicaid* rebates collected.

Net Medicaid spending is also expected to rise for some drugs launched in 2023 or later as manufacturers respond to the new Medicare provisions by setting higher launch prices for those drugs.

A drug's Best Price is the lowest price available to any purchaser excluding participating Part D plans and certain government entities. It reflects discounts, rebates, and other pricing adjustments, and is used to calculate a manufacturer's rebate to the Medicaid program.

Case: 24-1820 Document: 28-3 Page: 363 Date Filed: 07/12/2024

CBO Projects That, on Net, the Inflation Rebate Policy Will Lower the Deficit

Rebate payments, lower drug prices, and lower health insurance premiums in the commercial market will lower federal spending and increase federal revenues, according to CBO's estimates.

Higher prices in Medicaid are expected to offset some of that lowered spending.

CBO estimates that, overall, the inflation rebate policy will reduce the federal budget deficit by $8 billion in 2031 through the following effects:

- Part D spending will be $7 billion lower and Part B spending will be $3 billion lower than spending would have been without the policy.
- Lower commercial health insurance premiums will increase revenues and reduce spending by a combined $2 billion.
- Higher Medicaid spending and, to a lesser extent, higher spending by the Department of Defense will increase the deficit by $4 billion.

How the Redesign of the Part D Benefit Will Affect Medicare's Prices and the Deficit

Case: 24-1820 Document: 28-3 Page: 364 Date Filed: 07/12/2024

Before Redesign, the Standard Part D Benefit Had Four Coverage Phases

Deductible and initial coverage phases

- In the first phase, enrollees paid 100 percent of their drug costs up to the deductible set by statute.
- When enrollees' spending exceeded the deductible, enrollees entered the initial coverage phase and paid 25 percent of costs and their Part D plan paid 75 percent.

Coverage gap phase (for enrollees who did not receive the low-income subsidy)

- Enrollees whose total spending (by themselves and on their behalf by all payers) exceeded the initial coverage limit set by statute continued to pay 25 percent of drug costs; plans and manufacturers combined to pay the remainder.
- For brand-name drugs, the manufacturer provided a mandatory discount of 70 percent, and the Part D plan paid 5 percent.
- For generic drugs, the Part D plan paid 75 percent.

Catastrophic phase

- Enrollees whose out-of-pocket costs (including discounts received) exceeded the catastrophic threshold set by statute paid 5 percent of drug costs.
- Part D plans paid 15 percent and the federal government's share of drug costs (referred to as reinsurance) was 80 percent.

For a description of the Part D benefit design prior to enactment of the law and how it interacted with the incentives of market participants, see Congressional Budget Office, "Paying for Drugs in Medicare Part D Under Current Law and Under Proposals to Redesign the Program" (November 2021), www.cbo.gov/publication/57461.

Case: 24-1820 Document: 28-3 Page: 365 Date Filed: 07/12/2024

Part D Redesign Eliminates the Coverage Gap and Places Greater Liability for Part D Spending on Plans

The deductible phase of the benefit remains the same.

Enrollees entering the initial coverage phase still pay 25 percent of drug costs. But, starting in 2025, the plans' share falls to 65 percent of costs for brand-name drugs (other than those subject to negotiation), and the manufacturers provide a discount of 10 percent of total costs.

The coverage gap phase is eliminated.

The catastrophic phase starts when enrollees' out-of-pocket costs reach $2,000 and in this phase enrollees pay nothing:

- The federal government's share of drug costs falls from 80 percent to either 20 percent (for brand-name drugs) or to 40 percent (for generics).
- Manufacturers provide discounts of 20 percent for brand-name drugs, except drugs whose prices have been negotiated with the Secretary.
- Part D plans' share of drug costs increases from 15 percent to 60 percent.

The elimination of the 5 percent co-insurance requirement in the catastrophic phase occurs in 2024. Enrollees' out-of-pocket costs are capped at $2,000 per year beginning in 2025; that cap is adjusted annually thereafter at the projected rate of growth in Part D costs per enrollee.

JA771

Case: 24-1820 Document: 28-3 Page: 366 Date Filed: 07/12/2024

Premium Stabilization Limits Premium Growth From 2024 to 2029 and Permanently Lowers Premiums in Subsequent Years

Part D premiums are determined in part by a policy benchmark known as the base beneficiary premium, which is based on expected average benefit costs for all Part D enrollees. Although premiums that enrollees pay vary by plan, they tend to increase when the base beneficiary premium rises.

Under the new premium stabilization policy for Part D, growth in the base beneficiary premium is capped at 6 percent per year from 2024 through 2029. Although CBO expects that cap to slow premium growth on average, during those years some enrollees could still experience annual premium growth greater than 6 percent depending on their plan choices.

In 2030, the Secretary is required to permanently adjust the formula for the base beneficiary premium if its level in 2030 would otherwise be more than 6 percent higher than in 2029.

For additional information about how CBO analyzed the effects of the premium stabilization mechanism, see Congressional Budget Office, letter to the Honorable Jason Smith providing additional information about prescription drug legislation (August 4, 2022), https://www.cbo.gov/publication/58355.

JA772

Case: 24-1820 Document: 28-3 Page: 367 Date Filed: 07/12/2024

Eliminating the Coverage Gap Changes How Costs for Low-Income Enrollees Are Covered

In Part D, enrollees whose incomes and assets fall below specified thresholds are eligible for the low-income subsidy. That subsidy consists of two parts: a premium subsidy and a cost-sharing subsidy.

Under the previous standard benefit, the coverage gap phase for low-income enrollees differed from that for enrollees who did not receive the subsidy. For low-income enrollees in the coverage gap phase, all drug costs were assigned to the enrollee and were largely covered by the cost-sharing subsidy.

Under the Part D redesign, low-income enrollees have the same standard benefit as other enrollees, and the coverage gap is eliminated. As a result, the share of costs assigned to the enrollee and covered by the federal government decreases, while the shares covered by plans and manufacturers increase.

JA773

Case: 24-1820 Document: 28-3 Page: 368 Date Filed: 07/12/2024

CBO Projects That Certain Elements of Part D Redesign Will Reduce the Deficit

Reallocated Part D spending and reduced spending on Parts A and B are expected to put downward pressure on the deficit:

- The federal contribution to the cost-sharing subsidy and to spending in the catastrophic phase will decrease.
- Manufacturers will bear a greater share of total Part D costs through statutory discounts, which reduces subsidies from the federal government.
- Plans will have a stronger incentive to control costs because they will be responsible for a greater percentage of costs.
- Lower out-of-pocket costs for enrollees will lead to greater use of Part D drugs, which will reduce spending in Medicare Part A and Part B.

JA774

Case: 24-1820 Document: 28-3 Page: 369 Date Filed: 07/12/2024

Other Elements of Part D Redesign Will More Than Offset the Reductions, Leading to an Overall Deficit Increase, CBO Estimates

Increased federal subsidies, premium stabilization, and increased use of drugs put upward pressure on the deficit:

- Federal subsidies to Part D plans will rise as plans face greater liability for drug costs.
- The premium stabilization mechanism will increase federal spending.
- Part D enrollees will use more drugs because their out-of-pocket costs will be lower.

CBO projects an overall increase in the federal budget deficit of $2 billion in 2031:

- Part D spending will increase by $4 billion.
- Part A and Part B spending will decrease by $2 billion because of increased use of prescription drugs.

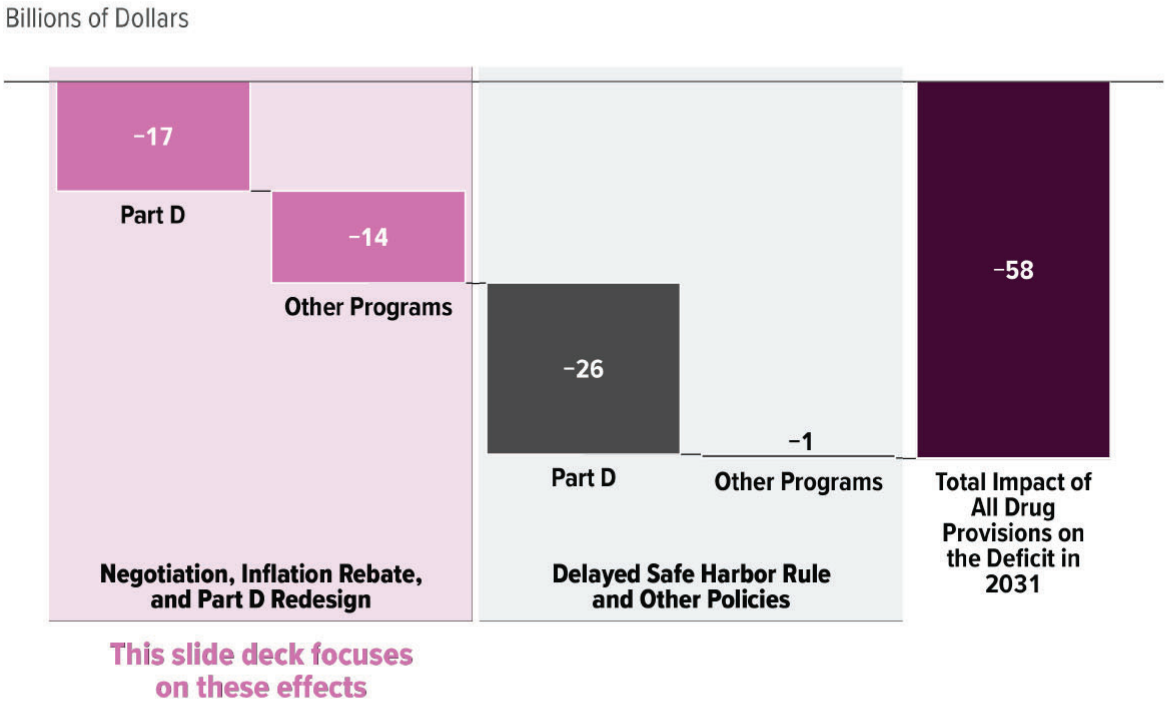
JA775

Case: 24-1820 Document: 28-3 Page: 370 Date Filed: 07/12/2024

How the Combined Effects of Negotiation, Inflation Rebates, and Part D Redesign Will Affect the Federal Budget

Case: 24-1820 Document: 28-3 Page: 371 Date Filed: 07/12/2024

CBO Estimates That Drug-Related Provisions Combined Will Reduce the Deficit by $58 Billion in 2031



Taken together, all drug-related provisions in the 2022 Reconciliation Act will reduce the federal deficit by an estimated **$58 billion** in fiscal year 2031.

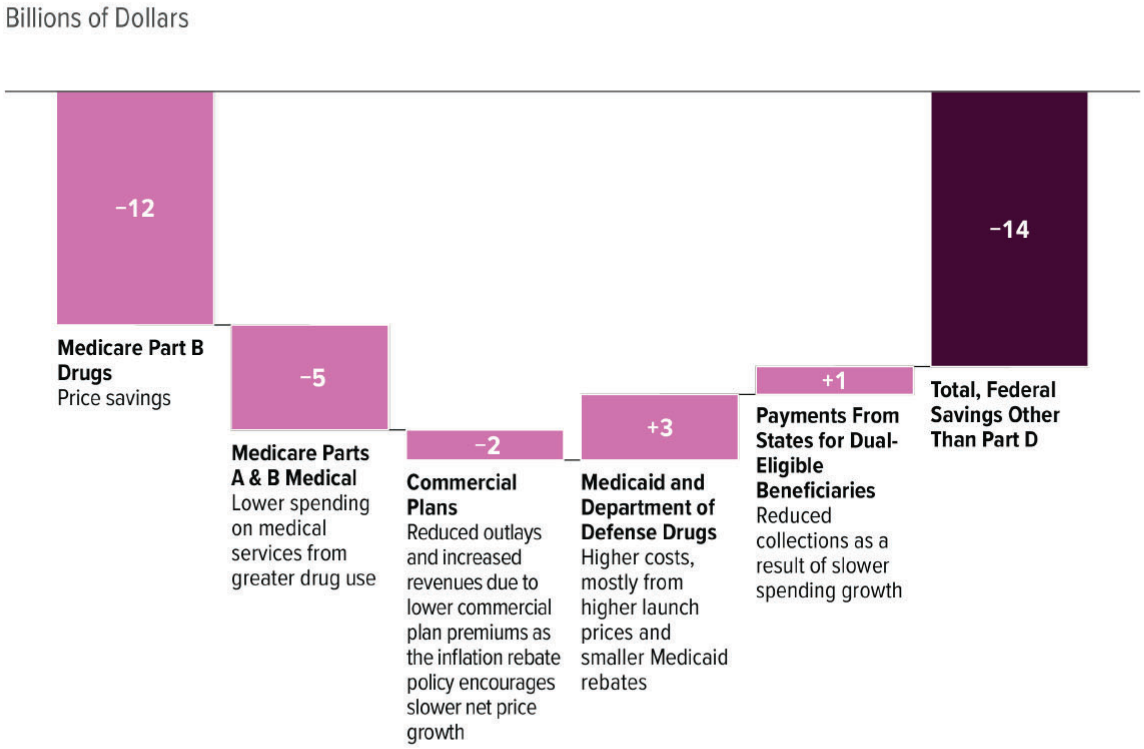
About half ($31 billion) of that reduction is attributable to the negotiation, inflation rebate, and Part D redesign provisions discussed in this slide deck, including **$17 billion** in Part D and **$14 billion** in other programs.

Nearly all of the remaining $27 billion is accounted for by reduced Part D spending from delaying implementation of the safe harbor rule.

JA777

Case: 24-1820 Document: 28-3 Page: 372 Date Filed: 07/12/2024

$14 Billion of the Deficit Reduction from the Three Key Drug Policies Comes From Outside of Part D



The **$14 billion** in other federal savings expected from the three key policies in 2031 are mostly driven by **$12 billion** in savings on Medicare Part B drugs. That includes $9 billion from the negotiation policy and $3 billion from the inflation rebate policy.

CBO estimates that spending on medical services covered under Medicare Parts A and B will decrease by **$5 billion** as a result of increased use of prescription drugs.

Lastly, changes in overall drug spending growth will increase tax revenues and interact with other federal programs. Taken together, those effects will increase the deficit by $3 billion. (Components do not sum to the total because of rounding.)

Dual-eligible beneficiaries are people who are enrolled in both Medicare and Medicaid.

JA778

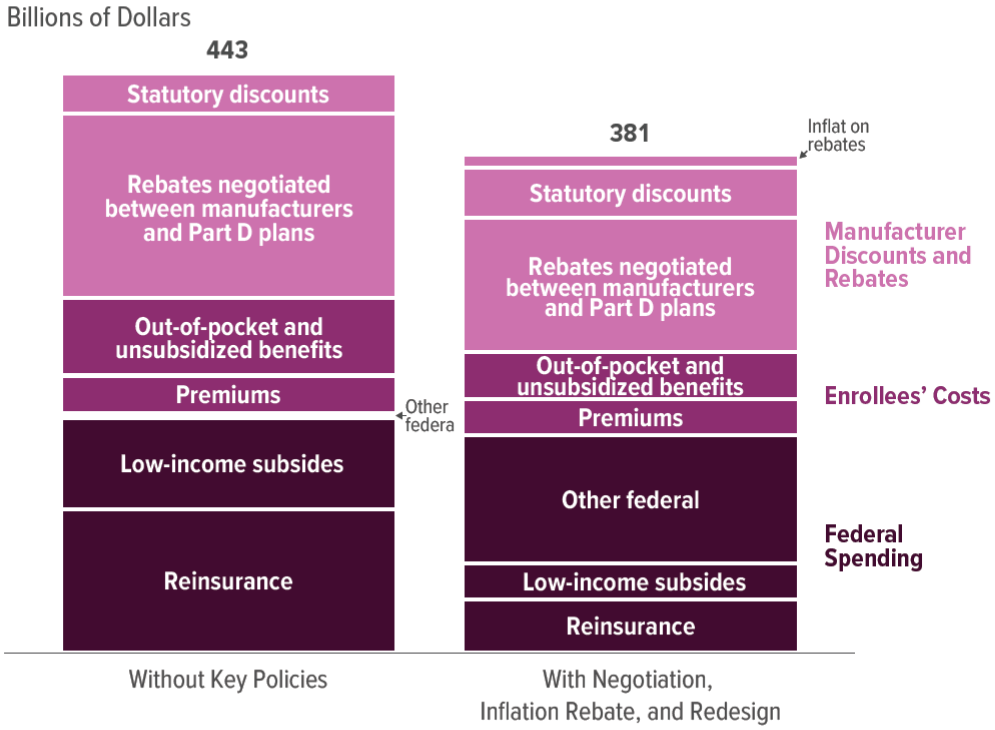
Case: 24-1820 Document: 28-3 Page: 373 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 374 Date Filed: 07/12/2024

How the Combined Effects of Negotiation, Inflation Rebates, and Part D Redesign Will Affect Spending by All Payers in Medicare Part D

JA779

CBO Projects That the Three Key Drug Policies Will Lower Total Part D Spending by $62 Billion in 2031



Total Part D drug spending at retail prices is projected to decrease by $62 billion (14 percent) in 2031, from **$443 billion** to **$381 billion**, because of price reductions for negotiated drugs and slower price growth from the inflation rebate policy.

Total Part D drug spending net of manufacturer discounts and rebates, which consists of enrollees' costs plus federal spending, is projected to decrease by $42 billion (15 percent), from $272 billion to $230 billion. Factors behind that decline include price reductions, slower price growth, and increased statutory discounts included in the Part D redesign.

Federal spending, net of premiums and inflation rebate receipts, accounts for $17 billion of that decrease. It is projected to decrease by 9 percent, from $183 billion to $166 billion. The percentage decline in federal spending is less than the percentage decline in overall drug spending because some of the decline in drug spending reduces enrollees' cost sharing.

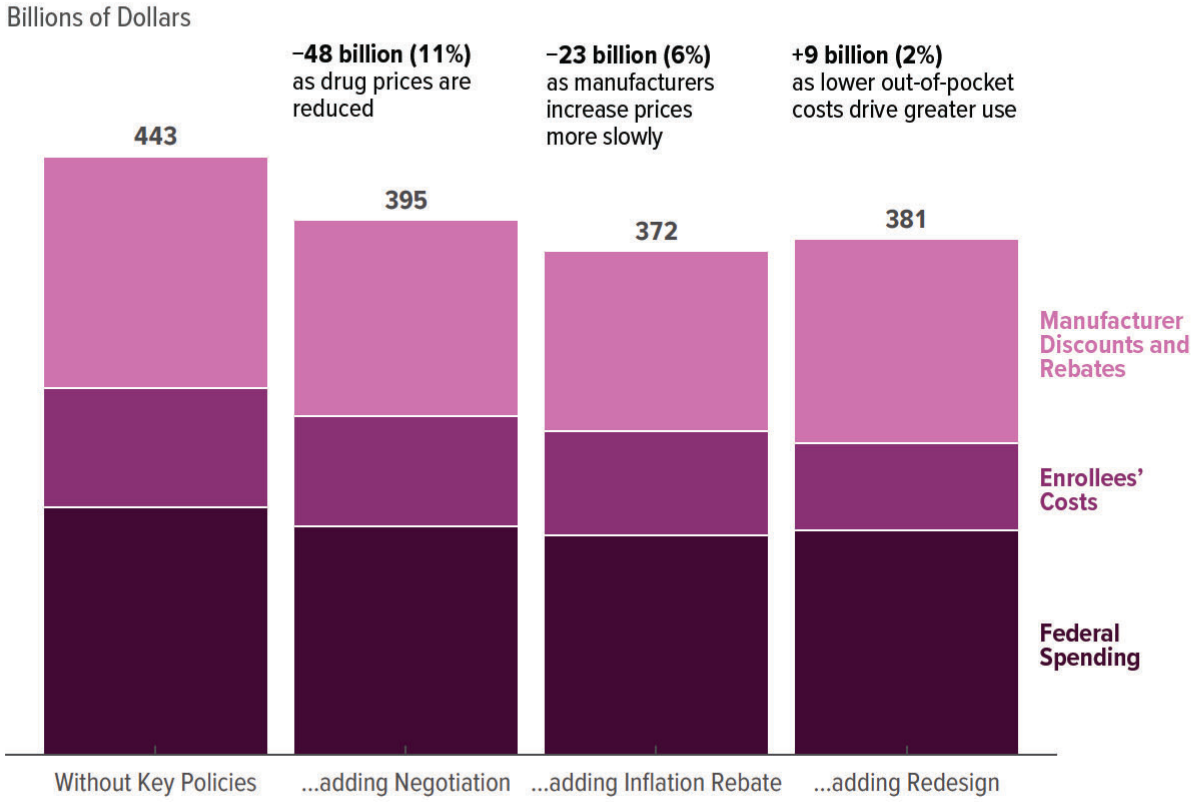
Low-income subsidies and reinsurance together are projected to decline from 98 percent to 41 percent of federal spending.

The "Without Key Policies" scenario reflects the delay of the safe harbor rule. "Other federal" includes the direct subsidy to Part D plans, subsidies to employers that provide drug coverage to Medicare enrollees, and new subsidies created by the Part D redesign.

JA780

Case: 24-1820 Document: 28-3 Page: 375 Date Filed: 07/12/2024

How Each of the Key Drug Policies Contributes to an Estimated $62 Billion Decline in Total Part D Spending



Responsible for an estimated **$48 billion** decrease in drug spending, the negotiation policy accounts for most of the overall $62 billion decrease in drug spending in 2031.

"Total Part D spending" is spending on Part D drugs at retail prices. The "Without Key Policies" scenario reflects the delay of the safe harbor rule.

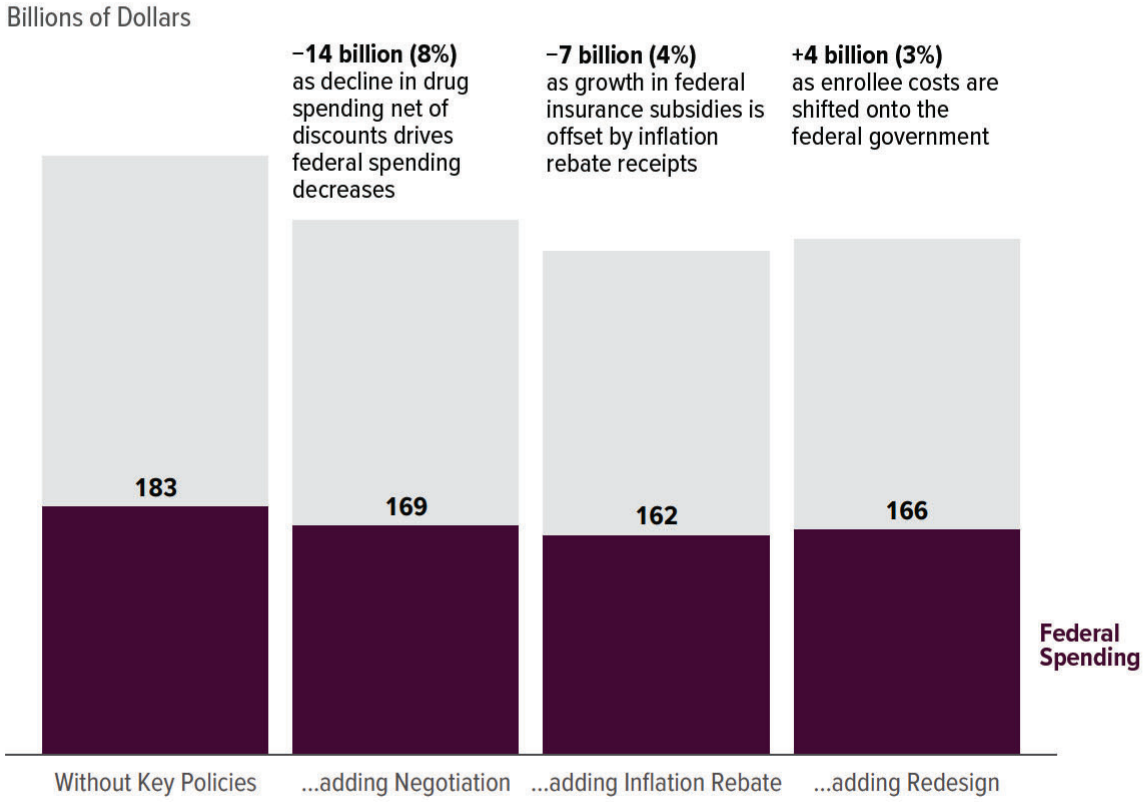
JA781

Case: 24-1820 Document: 28-3 Page: 376 Date Filed: 07/12/2024

Case: 24-1820 Document: 28-3 Page: 377 Date Filed: 07/12/2024

JA782

How Each of the Key Drug Policies Contributes to an Estimated $17 Billion Decline in Federal Part D Spending



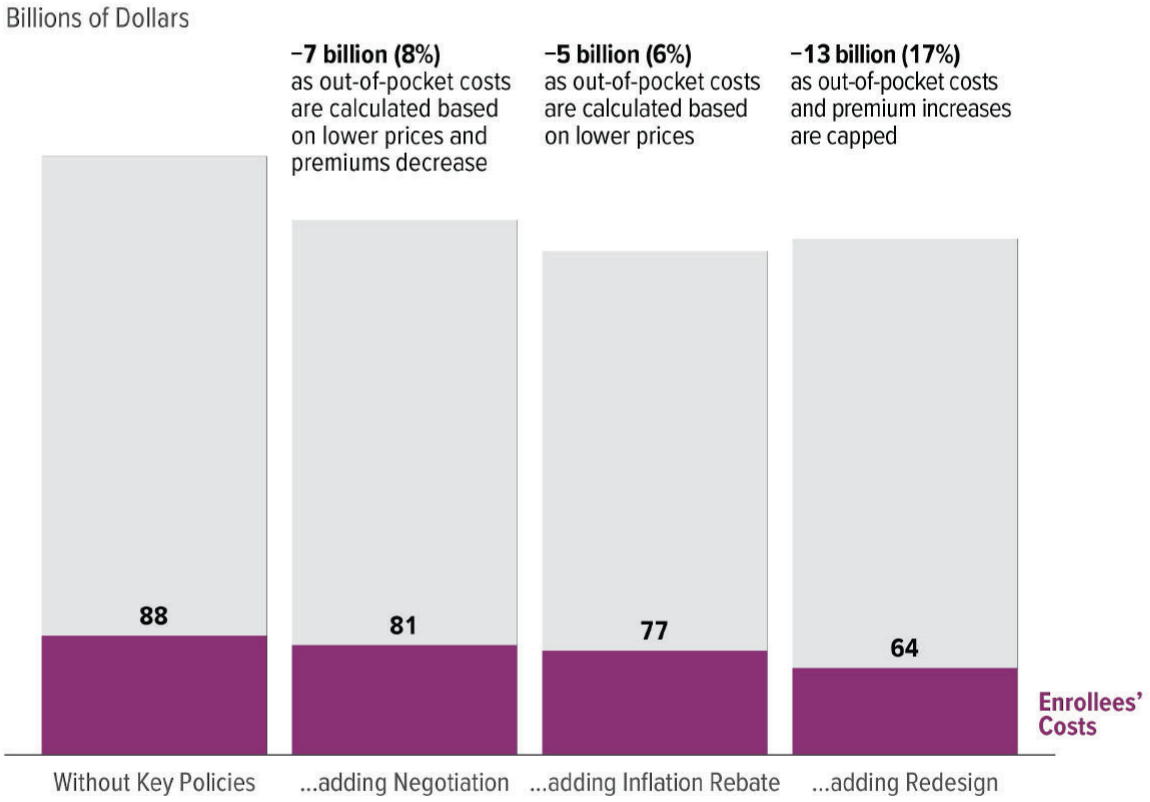
By lowering federal spending from **$183 billion** to **$169 billion**, the negotiation policy drives most of the $17 billion decrease in federal spending in 2031.

The "Without Key Policies" scenario reflects the delay of the safe harbor rule. "Federal spending" is drug spending at retail prices. Components do not sum to totals because of rounding.

Case: 24-1820 Document: 28-3 Page: 378 Date Filed: 07/12/2024

JA783

How Each of the Key Drug Policies Contributes to an Estimated $25 Billion Decline in Part D Enrollees' Costs



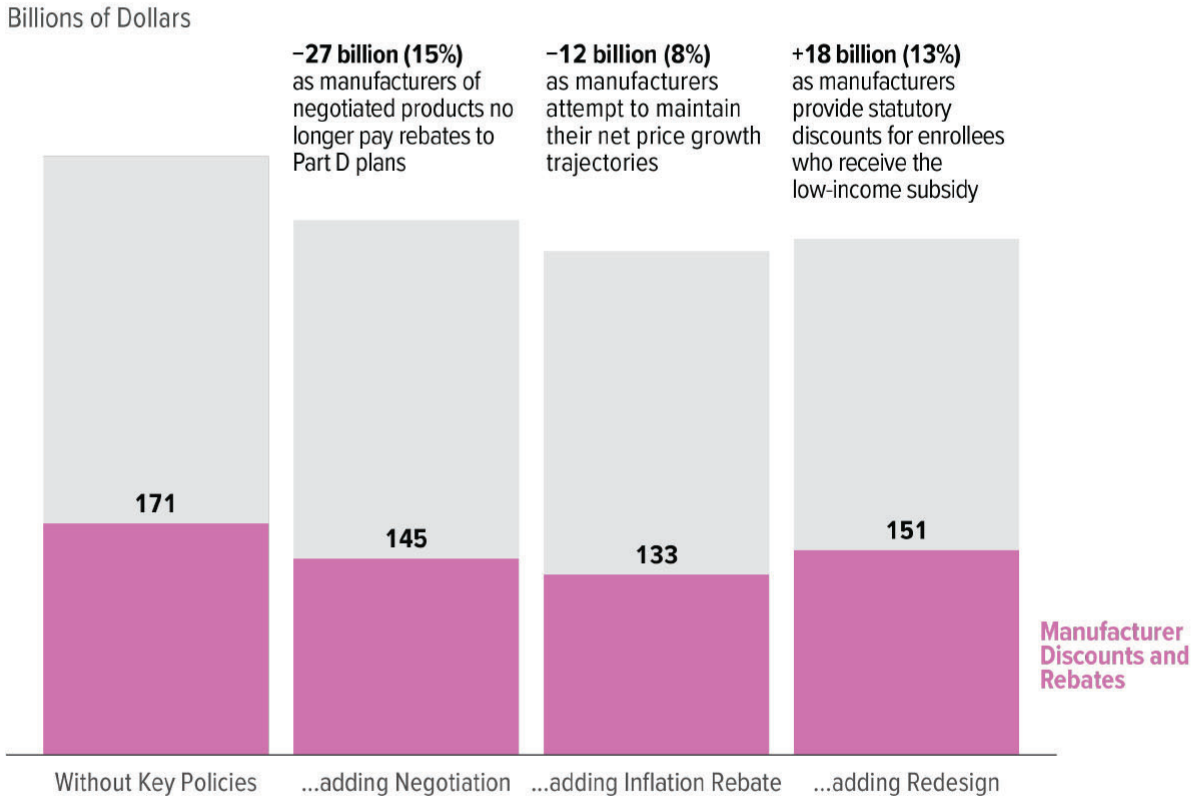
Lower costs for enrollees account for about 40 percent of the estimated $62 billion decrease in total Part D spending in 2031. By reducing enrollees' costs by **$13 billion**, the Part D redesign policy drives more than half of the $25 billion decrease in those costs in 2031.

The "Without Key Policies" scenario reflects the delay of the safe harbor rule. "Enrollees' Costs" comprise enrollee drug spending at retail prices. Components do not sum to totals because of rounding.

Case: 24-1820 Document: 28-3 Page: 379 Date Filed: 07/12/2024

JA784

How Each of the Key Drug Policies Contributes to an Estimated $20 Billion Decline in Manufacturer Discounts and Rebates



A decline of $20 billion in manufacturer discounts and rebates accounts for the rest of the estimated $62 billion decrease in total Part D spending in 2031. CBO estimates that the negotiation provision is the largest contributor to that $20 billion decline.

The "Without Key Policies" scenario reflects the delay of the safe harbor rule. Components do not sum to totals because of rounding.

About This Document

This document was prepared to enhance the transparency of CBO's work and to encourage external review of that work. In keeping with CBO's mandate to provide objective, impartial analysis, the document makes no recommendations.

Colin Baker, Scott Laughery, and Asha Saavoss prepared the document with guidance from Tamara Hayford and Paul Masi. Elizabeth Bass, Ezra Cohn, Carrie H. Colla, Ryan Greenfield, Stuart Hammond, Leo Lex (formerly of CBO), R. L. Rebach, Lara Robillard, Matt Schmit, Joshua Varcie, Chapin White, and Kate Young provided comments.

Jeffrey Kling, Robert Sunshine, and Phillip Swagel reviewed the document. Lora Engdahl edited it and Casey Labrack created the graphics. The document is available at www.cbo.gov/publication/58850.

CBO seeks feedback to make its work as useful as possible. Please send comments to communications@cbo.gov.

JA785

Case: 24-1820 Document: 28-3 Page: 380 Date Filed: 07/12/2024

Exhibit G

STATEMENT OF

CHIQUITA BROOKS-LASURE

ADMINISTRATOR

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

"LOWERING UNAFFORDABLE COSTS: LEGISLATIVE SOLUTIONS TO INCREASE TRANSPARENCY AND COMPETITION IN HEALTH CARE"

BEFORE THE

U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

APRIL 26, 2023

U.S. House Committee on Energy & Commerce

Subcommittee on Health

"Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care."

April 26, 2023

Chairs McMorris Rodgers and Guthrie, Ranking Members Pallone and Eshoo, and Members of the Subcommittee, thank you for the opportunity to discuss the Centers for Medicare & Medicaid Services' (CMS's) work to lower health care costs and increase price transparency across the health care system.

As the nation's largest payer for health care, CMS plays a key role in incentivizing high-quality care and smarter spending across the industry. CMS programs cover over 170 million people across the United States, including more than 92 million people enrolled in Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program, over 64 million people enrolled in Medicare, and over 16 million Americans who selected or were automatically re-enrolled in health insurance coverage through HealthCare.gov Marketplaces and State-based Marketplaces (SBMs) during the 2023 open enrollment.[1,2] Efforts across the Agency are based on a foundation of goals that aim to advance health equity, eliminate avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and provide the care and support that our enrollees need to thrive.

We greatly appreciate the additional tools and resources provided by Congress through historic legislation such as the Patient Protection and Affordable Care Act (P.L. 111-148), and more recently, the American Rescue Plan Act (P.L. 117-2), the Inflation Reduction Act (P.L. 117-169), the Bipartisan Safer Communities Act (P.L. 117-159) and the Consolidated Appropriations Acts, 2021 (P.L. 116-260), 2022 (P.L. 117-103), and 2023 (P.L. 117-328). Thanks to provisions in these important laws, the Administration has made tremendous progress toward increasing

[1] CMS FY 2022 Financial Report: https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2022.pdf
[2] CMS Press Release, "Biden-Harris Administration Celebrates the Affordable Care Act's 13th Anniversary and Highlights Record-Breaking Coverage" https://www.cms.gov/newsroom/press-releases/biden-harris-administration-celebrates-affordable-care-acts-13th-anniversary-and-highlights-record

access to affordable treatments, strengthening the Medicare program, lowering prescription drug costs, and expanding access to health coverage in Medicaid and through the Marketplace.

CMS is committed to building on the work we have done to date, and is continuing to find ways to address rising health care costs—including both costs to the health care system overall and out-of-pocket costs borne by patients—in a way that allows us to advance health equity, expand access, improve health outcomes, and increase transparency.

Implementing the Inflation Reduction Act and Lowering Drug Costs

Drug costs account for a growing portion of overall health care costs, and Americans are often forced to make difficult decisions between paying for their prescriptions or other basic needs, like paying their rent or putting food on the table. On average, one in four Americans who take prescription drugs struggle to afford their medications. Nearly 3 in 10 American adults who take prescription drugs say that they have skipped doses, cut pills in half, or not filled prescriptions due to cost.[3] In 2021, prescription drug spending increased by 7.8% to $378 billion, compared to 3.7% in 2020.[4] CMS is responding to this growing problem by taking proactive steps to reduce what Americans pay at the pharmacy counter and to reduce overall drug spending within our programs.

Among other efforts, CMS is hard at work implementing provisions of the Inflation Reduction Act (IRA), which lowers prescription drug spending for millions of people with Medicare, redesigns the Part D program, keeps prescription drug premiums stable, and strengthens the Medicare program both now and in the long run. Thanks to this work, people with Medicare prescription drug coverage are already beginning to see lower out-of-pocket costs. For example, beginning in January of this year, people with Medicare prescription drug coverage now have coverage of vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), such as the shingles vaccine, at no cost. Starting October 1, 2023, most adults enrolled in Medicaid or CHIP will also have access to ACIP-recommended adult vaccines with no cost-

[3] Executive Order on Lowering Prescription Drug Costs for Americans, https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription-drug-costs-for-americans/
[4] National Health Expenditure Data Fact Sheet, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet

guidance, and we will continue to provide multiple comment opportunities for members of the public, people with Medicare and their families, beneficiary and consumer advocates, pharmaceutical manufacturers, health care providers, and other stakeholders to provide input as we move forward with implementing the law.

Medicare Prescription Drug Inflation Rebate Program

CMS is also implementing the provisions of the IRA that discourage drug companies from increasing their prices faster than the rate of inflation. The Medicare Prescription Drug Inflation Rebate Program will require manufacturers to pay rebates to the Medicare Trust Fund in cases of price increases for certain drugs that exceed inflation, particularly brand name drugs, which make up 80 percent of all prescription drug spending. Since one of the primary drivers of increased prescription drug spending has been increases in spending per prescription, requiring rebates for price increases above inflation for drugs already on the market may help reduce future growth in Medicare prescription drug spending. Thanks to these policies, CMS is already reducing coinsurance for some people with Medicare Part B coverage.

Ensuring Sustainability Across CMS Programs

We are committed to fulfilling our obligation under the law to be a good steward of CMS programs, ensuring that taxpayer dollars are spent appropriately and improving the long-term sustainability of these programs.

Strengthening Medicare

The Administration is working to strengthen the Medicare program for current and future generations, and our efforts are getting results. This year's Medicare Board of Trustees Report estimates that the solvency of the Medicare Hospital Insurance Trust Fund has been extended by three years since last year's report.[6] Adopting the proposals in the President's FY 2024 Budget would further extend the solvency of the Medicare Hospital Insurance Trust Fund by at least 25 years by making the wealthy pay their fair share in taxes and by furthering efforts to lower prescription drug costs. Proposals in the budget would build on efforts in the Inflation Reduction

[6] 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, https://www.cms.gov/oact/tr/2023

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

JANSSEN PHARMACEUTICALS, INC., *Plaintiff*, v. XAVIER BECERRA, Secretary of Health and Human Services, *et al.*, *Defendants*.	Civil Action No. 23-cv-03818-ZNQ-JBD

DECLARATION OF BLASINE PENKOWSKI IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I, Blasine Penkowski, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am Chief Strategic Customer Officer for the North American operations of the Janssen Pharmaceutical Companies ("Janssen Companies"), which include Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen"), and have held that position since January 2015. I submit this declaration in support of Janssen's Motion for Summary Judgment.

2. As Chief Strategic Customer Officer, I am responsible for, among other things, Janssen's customer strategy development and Janssen's operations relating to the Drug Price Negotiation Program (the "Program") established by the Inflation Reduction Act (the "Act"). Prior to my current position, I served as Vice President,

Customer Strategy at Janssen North America and in senior strategic leadership roles at AbbVie Inc. and Abbott Laboratories.

3. This declaration is based on my personal knowledge regarding the effects of the Program on Janssen, as well as information assembled by authorized Janssen employees, upon whom I have relied. Subject to these limitations, the facts contained in this Declaration are true and correct to the best of my knowledge, information, and belief.

Janssen's Xarelto® Products

4. Since 2016, the Janssen Companies have invested more than $65 billion in researching and developing innovative new drugs and biologics, including $11.6 billion in 2022 alone.[1]

5. These investments have allowed the Janssen Companies to obtain Food and Drug Administration ("FDA") approval for eight new medications and 52 additional indications or new product formulations since 2016.

6. Janssen is the exclusive U.S. licensee of the patents that claim rivaroxaban and its use, and it has the exclusive right to market Xarelto® (rivaroxaban) products in the United States. Pursuant to that license, Janssen

[1] Additional details regarding the Janssen Companies' investments in pioneering drug treatments are available in the 2022 U.S. Pricing Transparency Brief, available at https://transparencyreport.janssen.com/_document/2022-janssen-transparency-report-pdf?id=00000188-267e-d95e-abca-7e7e58750000.

manufactures and sells Xarelto®, a direct oral anticoagulant that treats and helps prevent blood clots and reduces the risk of stroke.

7. In 2022, nearly 3 million patients in the United States filled a combined total of almost 11 million prescriptions for Xarelto®. Medicare has accounted for more than half of Xarelto® prescriptions between 2021 and 2023, with Medicaid and Medicare together accounting for more than 60% of U.S. Xarelto® prescriptions during that period.

Janssen's Broader Participation in Medicare and Medicaid

8. Including its Xarelto® products, Janssen manufactures and sells 21 drugs through Medicare and Medicaid, measured by unique New Drug Application and Biologic License Application Numbers.[2] Including Janssen's drugs, the broader group of Janssen Companies manufacture and sell 53 drugs through Medicare and Medicaid, measured in the same way.

9. The sale of products in Medicare and Medicaid made up approximately 40% of the Janssen Companies' gross pharmaceutical revenues in 2022. For Janssen specifically, the share of Medicare and Medicaid sales was even more pronounced, with approximately 50% of prescriptions filled for Janssen products and approximately 65% of its gross sales in 2022 attributable to those federal programs.

[2] This figure includes Ditropan XL (NDA 020897) which, while discontinued, remains available in Medicare and Medicaid.

10. In 2023, the Janssen Companies estimate that more than 4.5 million patients will fill prescriptions for the Janssen Companies' pharmaceutical products. Millions of those patients will obtain Janssen products, like Xarelto®, through Medicare and Medicaid.

11. Because Medicare and Medicaid comprise a very large portion of both the U.S. pharmaceutical market and Janssen's business, Janssen's ability to participate in these markets is critical to its continued ability to innovate and compete.

The Program's Effects on Janssen

12. Xarelto® is a self-administered drug marketed by Janssen through Medicare Part D.

13. Because FDA approved Xarelto® on July 1, 2011, it will have been approved for at least seven years as of September 1, 2023, and thus will constitute a "qualifying single-source drug" under the Program. *See* 42 U.S.C. § 1320f-1(e)(1)(A). CMS has announced that it "will select" the ten drugs with the highest Medicare Part D sales for the Program's first year. *See* Declaration of Jeffrey S. Chiesa ("Chiesa Decl.") Ex. A § 30.3.

14. Independent analyses have consistently concluded that Xarelto® is among the top ten drugs with respect to Medicare Part D expenditures, and that CMS will therefore select Xarelto® for the Program in 2023. *See, e.g.*, Chiesa Decl. Ex.

C (identifying Xarelto® as the second-highest drug among the top ten and thus as a drug "[s]ubject to negotiation" for the Program's first year); Expert Declaration of Professor Craig Garthwaite, *Nat'l Infusion Center Ass'n et al. v. Becerra*, No. 1:23-cv-00707, ECF No. 35-1, App'x D (W.D. Tex. Aug. 10, 2023) (similarly identifying Xarelto® as the second-highest drug among the top ten and thus as one of the ten drugs that will be subject to the Program beginning in September 2023).

15. When CMS selects the ten highest-spend Medicare Part D qualifying single-source drugs for the Program on September 1, 2023, Xarelto® will be selected, based on the studies noted above and additional Medicare spending data available to Janssen.

16. Once CMS selects Xarelto® for the first year of the Program, Janssen will have until October 1, 2023, to sign a "Manufacturer Agreement" to "negotiate" a "maximum fair price" with CMS. *See* 42 U.S.C. §§ 1320f(d)(2)(A), 1320f-2. Failing to sign that Agreement would subject Janssen to a daily "excise tax" penalty on every domestic sale of Xarelto® both in and out of Medicare. *See* 26 U.S.C. § 5000D.

17. For the first 90 days of noncompliance, Janssen would have to pay a daily "excise tax" penalty equal to 185.71% of Xarelto® gross U.S. sales. Based on projected sales data, that penalty would amount to more than $50 million per day, or more than $4.5 billion over the course of the first 90 days of noncompliance.

18. If Janssen were to not comply with the Program's requirements for longer than 270 days, domestic sales of Xarelto® would be subject to a 1900% daily "excise tax" penalty. At this rate, and based on projected sales data, Janssen would be liable for penalties more than $600 million per day. In total, the penalties for the first year of noncompliance would amount to more than $90 billion.

19. These projected tax burdens are in line with what Janssen would have owed had the "excise tax" penalty been applied to Janssen's Xarelto® sales for 2022. Based on actual Xarelto® sales data, if the "excise tax" penalty had applied beginning on the first day of that year and continued in effect through the final day of that year, Janssen's total liability would have been more than $75 billion.

20. The economic burden of the "excise tax" penalty would be so severe that during the first year of noncompliance the penalty would be more than three times greater than the 2022 total U.S. adjusted net earnings of Johnson & Johnson, Janssen's ultimate parent company, across all of Johnson & Johnson's products (including non-pharmaceutical products).

21. Aside from submitting to the Program, the only way to avoid these penalties is for Janssen, to withdraw all of its products from both Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c). That step would mean removing all 21 of Janssen's Medicare and Medicaid drugs from those programs, losing at least half of the prescriptions filled for Janssen's products, and thus forgoing access to a

substantial proportion of Janssen's annual revenues (approximately 65% of gross sales in 2022). Most detrimentally, forcing Janssen to withdraw from Medicare and Medicaid would leave millions of patients at risk without insurance coverage for the Janssen medicines they have come to depend on.

22. Given the economic and patient-harming consequences of not submitting to the Program, Janssen will have no choice but to comply once CMS selects Xarelto®—a course of action Janssen would not take but for the punitive consequences of not complying.

23. Accordingly, Janssen's participation in the Program is not voluntary, nor is there any mutual "agreement" with CMS regarding Janssen's participation in the Program. Despite its views, Janssen will be forced to convey that the Program is voluntary and that it agreed to participate by signing the Manufacturer Agreement with CMS.

24. After Janssen is compelled to sign the Manufacturer Agreement, the "negotiation" phase of the Program begins. *See* 42 U.S.C. § 1320f-3. Janssen disagrees that this process will involve a "negotiation" because an actual negotiation produces a binding contract only when both parties freely agree on its terms, especially price. Under the Program, however, Janssen will have no choice but to accept the "maximum fair price" and other terms (such as the provisions of the Manufacturer Agreement) unilaterally dictated by CMS.

25. The Act also states that the Program will result in a "maximum fair price" for selected drugs like Xarelto®. But Janssen disagrees that the price dictated through the Program will be "fair." Because Xarelto® will fall within the Act's definition of a short-term monopoly drug, it will be subject to an automatic discount of at least 25% from the average price paid by non-federal wholesalers for Xarelto®. *See id.* § 1320f-3(c)(3)(A). The Act requires CMS to set the "lowest maximum fair price" below the statutory ceiling, without any floor (i.e., all the way down to $0). *See id.* § 1320f-3(b)(1). As a result of these provisions, the Program will result in a "maximum fair price" that is far below what Janssen views as "fair."

26. Despite its views, the Act and the Manufacturer Agreement will force Janssen to convey that it will engage in voluntary "negotiations" with CMS and that those "negotiations" will result in a "fair" price for Xarelto®. And because CMS will compel Janssen to sign an addendum to the Manufacturer Agreement at the conclusion of the "negotiation" process memorializing this purportedly agreed-upon price, Janssen will again be forced to convey the Government's views rather than its own.

27. By depriving Janssen of the ability to earn anything resembling market returns on Xarelto® products, the Act will significantly undermine Janssen's ability to innovate and compete over the long-term. In particular, the Act will limit the ability of Janssen and the Janssen Pharmaceutical Companies to develop pioneering

new drugs, which in turn generate the revenues necessary to support development of the next generation of transformational and accessible treatments. As a result, the Act will undermine Janssen's ability to improve human health for patient populations with unmet medical needs.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 16th day of August, 2023.

Blasine Penkowski
Chief Strategic Customer Officer, Janssen North America
Janssen Pharmaceuticals, Inc., as part of the Janssen Pharmaceutical Companies
Titusville, New Jersey

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2024, the foregoing was electronically filed with the Clerk of Court using the appellate CM/ECF system.

Dated: July 12, 2024

/*s*/ Jacob (Yaakov) M. Roth
Jacob (Yaakov) M. Roth

Counsel for Appellant Bristol Myers Squibb Co.