[ORAL ARGUMENT NOT YET SCHEDULED]

Nos. 19-5048, 19-5198

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN HOSPITAL ASSOCIATION, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, Secretary of Health & Human Services, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia

OPENING BRIEF FOR APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs-Appellees are the American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals, Northern Light Health, Henry Ford Health System, and Fletcher Hospital, Inc. (d/b/a Park Ridge Health).

Defendants-Appellants are Alex M. Azar II, in his official capacity as Secretary of Health & Human Services, and the United States Department of Health & Human Services.

The Federation of American Hospitals participated as amicus curiae in district court.

B. Rulings Under Review

The rulings under review are the opinion and order entering final judgment on July 10, 2019 (Dkt. Nos. 58, 59); and all prior orders and decisions that merge into the final judgment, including the December 27, 2018 opinion and order (Dkt. Nos. 24, 25), and the May 6, 2019 opinion and order (Dkt. Nos. 49, 50). The rulings were issued by the Honorable Rudolph Contreras in Case No. 1:18-cv-02084 (D.D.C.). The December 27, 2018 opinion is reported at 348 F. Supp. 3d 62. The May 6, 2019 opinion is unreported but available at 2019 WL 1992868. The July 10, 2019 opinion is unreported but available at 2019 WL 3037306.

C. Related Cases

This Court previously issued an opinion involving the same dispute between the same parties. *See American Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018).

In this case, the district court styled its December 27, 2018 order as a permanent injunction, although the order did not enjoin any conduct. The government filed a notice of appeal as a protective measure. On the government's motion, this Court put that appeal into abeyance pending further district court proceedings. After final judgment was entered, this Court granted the government's motion to consolidate the earlier appeal (No. 19-5048) with the appeal from final judgment (No. 19-5198).

We are not aware of any pending related cases within the meaning of D.C. Circuit Rule 28.

s/ Laura E. Myron
LAURA E. MYRON

TABLE OF CONTENTS

Page

ARGUMENT:

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Other Authorities:

GLOSSARY

APA	Administrative Procedure Act
AHA	American Hospital Association
CMS	Centers for Medicare & Medicaid Services
GAO	Government Accountability Office
HHS	U.S. Department of Health & Human Services
OPPS	Outpatient Prospective Payment System

INTRODUCTION

Under the Outpatient Prospective Payment System (OPPS), the Department of Health and Human Services (HHS) sets Medicare payment rates through annual notice-and-comment rulemaking, based on considerations that are designed to approximate the costs incurred by efficient providers. In 2015 and 2016 reports, the Government Accountability Office (GAO) and the Medicare Payment Advisory Commission found that Medicare payments for certain drugs were far higher than the costs incurred by providers known as "340B hospitals." Thus, in the annual OPPS rules issued for the 2018 and 2019 years, HHS reduced Medicare's payments for those drugs so as to bring the payments in line with the acquisition costs incurred by 340B hospitals. Because OPPS rates are budget neutral, HHS redistributed the savings by increasing Medicare payments for other services during those years.

The Medicare statute expressly precludes judicial review of HHS's adjustments to OPPS rates. In *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), this Court indicated that it would construe that bar to allow limited review of claims of *ultra vires* action. This Court never applied that reasoning to invalidate any OPPS rate, however, and this Court recently clarified that *ultra vires* review is permitted only when "the statutory preclusion of review is implied rather than express" and "the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory." *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 509-10 (D.C. Cir. 2019).

Neither of those conditions is satisfied in this case. The Medicare statute's preclusion of review is express rather than implied, and the district court was mistaken to declare that the adjustment to the Medicare rate for drugs acquired by 340B hospitals is *ultra vires*. That adjustment furthered the statutory objective of setting Medicare payment rates that reflect hospital acquisition costs. The district court did not suggest that the rate adjustment failed to accomplish that end or that 340B hospitals were not being compensated for their acquisition costs. As HHS noted in the preamble to the 2018 rule, no hospital claimed that the adjusted rate would undercompensate it for its acquisition costs. *See* 82 Fed. Reg. 52,356, 52,500 (Nov. 13, 2017).

The district court incorrectly concluded that a provision of the Medicare statute, found at 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II), prohibits HHS from making an adjustment that aligns Medicare payments to 340B hospitals with the hospitals' acquisition costs. Congress did not impose any such prohibition, which would seriously undermine the equitable distribution of Medicare funds. HHS's correction of the over-compensation for the drugs at issue here allowed the agency to redistribute $1.6 billion in savings annually, resulting in a 3.2% increase in the Medicare payment rates for non-drug items and services during the years at issue here. *See* 82 Fed. Reg. at 52,623.

The district court misunderstood the Medicare provision that sets a default payment rate of 106% of a drug's average sales price. That default rate reflects the

reasonable assumption that, in many cases, the average sales price will reflect a hospital's acquisition costs and overhead costs. The Medicare statute does not require that HHS make payments at that rate when, as here, evidence shows that the rate would result in significant overpayments. On the contrary, the Medicare statute directs HHS to revise OPPS rates annually to take into account "new cost data," 42 U.S.C. § 1395*l*(t)(9)(A), and empowers HHS to make "adjustments as determined to be necessary to ensure equitable payments," *id.* § 1395*l*(t)(2)(E). And the provision that sets the default rate of 106% of average sales price explicitly provides that the rate be "calculated and adjusted by the Secretary as necessary for purposes of this paragraph," which is to compensate providers for the average acquisition cost of drugs. *Id.* § 1395*l*(t)(14)(A)(iii)(II).

The adjustment at issue here is plainly reasonable and within HHS's authority, and, if reviewable, would pass muster under the standards of the Administrative Procedure Act (APA). Plaintiffs certainly have not demonstrated the "patent violation of agency authority" that would constitute *ultra vires* action. *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016); *see also DCH Reg'l*, 925 F.3d at 509-10.

STATEMENT OF JURISDICTION

Plaintiffs challenged an adjustment to the Medicare Part B payment rates for drugs acquired by 340B hospitals for the 2018 and 2019 calendar years. They invoked the district court's jurisdiction under 28 U.S.C. § 1331 and 42 U.S.C. § 405. *See* JA19. In *American Hospital Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018) (*AHA I*), this Court held that plaintiffs could not bring a pre-enforcement challenge to the 2018 payment rate before the adjusted rate took effect. Plaintiffs subsequently renewed their challenge in the context of reimbursement claims. On December 27, 2018, the district court declared that the rate reduction was *ultra vires* and therefore not subject to the Medicare statute's preclusion of review, and ordered briefing on remedy. *See American Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62 (D.D.C. 2018); *see also* JA61-96. On May 6, 2019, the district court remanded the matter to HHS with instructions to devise a remedy, indicating that it would retain jurisdiction to oversee HHS's progress. *See* JA131. On July 10, 2019, on the government's motion for reconsideration, the district court entered final judgment and relinquished jurisdiction in order to facilitate this appeal. JA152; JA153-57.

The government filed a timely notice of appeal on July 11, 2019. JA158. This Court has appellate jurisdiction under 28 U.S.C. § 1291. *See North Carolina Fisheries Ass'n v. Gutierrez*, 550 F.3d 16, 19-20 (D.C. Cir. 2008) (explaining that although a remand order is ordinarily not "final" for purposes of appeal under 28 U.S.C. § 1291, "there is a limited exception permitting a government agency to appeal immediately

rather than bear significant expenses that cannot be recovered or take action pursuant to the remand that cannot be reversed if it is later determined that the order was improper") (citing *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 330 (D.C. Cir. 1989)).

STATEMENT OF THE ISSUE

Whether the district court erred in declaring that an adjustment to the Medicare Part B payment rates for certain drugs for the 2018 and 2019 calendar years exceeded HHS's authority under 42 U.S.C. § 1395*l*(t)(14) ("paragraph 14").

PERTINENT STATUTES AND REGULATIONS

Pertinent provisions are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

I. Statutory Background

A. The Medicare Outpatient Prospective Payment System

The Medicare program provides federally funded medical insurance to the elderly and disabled. *Amgen, Inc. v. Smith*, 357 F.3d 103, 105 (D.C. Cir. 2004). Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. Part B is a voluntary program that provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* at 105-06.

Medicare pays most hospitals through the inpatient prospective payment system, which is covered by Medicare Part A, and the outpatient prospective payment system, which is covered by Medicare Part B. Under these systems, Medicare pays

providers for a given service at a rate that is designed to approximate the costs incurred by efficient providers. *Amgen*, 357 F.3d at 106; *see also Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994).

This suit involves outpatient prospective payment rates, which are set each year through notice-and-comment rulemaking. The rates are calculated through a formula that sets payment weights for the provision of certain services (or certain groups of clinically similar services) based on the mean or median costs of providing such services in past years, with adjustments for regional cost variations and other specified factors. *Amgen*, 357 F.3d at 106. The Medicare statute vests HHS with broad authority to make "other adjustments as determined to be necessary to ensure equitable payments," *id.* (quoting 42 U.S.C. § 1395*l*(t)(2)(E)), and directs HHS not less often than annually to revise components of the OPPS to take into account (*inter alia*) "new cost data," 42 U.S.C. § 1395*l*(t)(9)(A). The Medicare statute generally requires that OPPS adjustments be budget neutral, which means that an increase in rates for particular services must be offset by a reduction in rates for other services. *Amgen*, 357 F.3d at 112; *see, e.g.*, 42 U.S.C. § 1395*l*(t)(2)(E), (t)(9)(B), (t)(14)(H).

The authority to make equitable adjustments to Medicare payment rates reflects HHS's "significant expertise" and "judgment grounded in policy concerns" over Medicare's "complex and highly technical regulatory program." *Amgen*, 357 F.3d at 106. The Medicare statute expressly precludes administrative and judicial review of

such adjustments (and other aspects of OPPS). *See* 42 U.S.C. § 1395*l*(t)(12)(A), (C).[1] That Congress intended to preclude judicial review of the Secretary's adjustments to prospective payment amounts is "unsurprising," because "review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year," and "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere." *Amgen*, 357 F.3d at 112. HHS expected to process more than 110 million OPPS claims for the 2018 year alone. JA98-99 (¶¶ 3, 7) (Richter Decl.).

B. OPPS Rates For "Specified Covered Outpatient Drugs"

In the period leading up to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, concerns were expressed about the adequacy of Medicare Part B payments for certain innovative pharmaceutical products. *See* GAO, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons*

[1] Paragraph 12(A) of section 1395*l*(t) precludes review of "adjustments" made under paragraph 2, which gives HHS authority to make various "adjustments as determined to be necessary to ensure equitable payments." Paragraph 12(C) precludes review of "periodic adjustments made under paragraph (6)." There is no dispute that this reference to paragraph 6 is a scrivener's error that should have been a reference to paragraph 9, which directs HHS to revise Medicare rates not less than annually. *See American Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 77 n.13 (D.D.C. 2018). Adjustments made under paragraph 14, which is at issue here, are a subset of the adjustments made under paragraph 9. *See* 42 U.S.C. § 1395*l*(t)(14)(H) (indicating that Medicare payments under paragraph 14 were exempt from paragraph 9's budget-neutrality requirement for a two-year transitional period and became subject to that requirement beginning in 2006).

and Outpatient Rate-Setting Challenges for CMS 6 (Apr. 2006), https://www.gao.gov/assets/250/249967.pdf (GAO-06-372) (reviewing the history). The 2003 amendments addressed those concerns by directing HHS to establish a new payment policy for "specified covered outpatient drugs," which were newly introduced drugs used to treat or diagnose serious conditions, such as cancer, in an outpatient hospital setting. *Id.* at 1-2.[2]

The new payment policy was codified as paragraph 14 of 42 U.S.C. § 1395*l*(t). As noted above, OPPS rates are generally designed to approximate the costs incurred by efficient providers. Paragraph 14 follows that model and directs HHS to make Medicare payment rates equal to the "average acquisition cost" incurred by hospitals for specified covered outpatient drugs. Paragraph 14 directed the GAO to conduct a survey in 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug, and to furnish data from these surveys for HHS to use in setting the payment rates for 2006. 42 U.S.C. § 1395*l*(t)(14)(D)(i)(I). Paragraph 14 further directed the GAO to recommend to HHS the frequency and methodology of subsequent surveys, *id.* § 1395*l*(t)(14)(D)(i)(II), and directed HHS to conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug, which, in turn, would inform the Secretary's calculation of an

[2] Specified covered outpatient drugs are a form of separately payable drugs, which means they are not bundled with other services and are instead reimbursed on a drug-by-drug basis.

estimate of the average hospital acquisition cost for each specified covered outpatient drug, *id.* § 1395*l*(t)(14)(D)(ii), (iii). And paragraph 14 provided that, beginning with the 2006 year, the Medicare payment amount for each specified covered outpatient drug "shall be equal"

> to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered [outpatient] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D).

Id. § 1395*l*(t)(14)(A)(iii)(I) ("subclause I"). Thus, under subclause I, Congress instructed HHS to base the Medicare payment amount on average acquisition cost, as informed by hospital survey data.

Congress directed GAO to recommend the frequency of future surveys, and provided an alternative methodology for HHS to use in setting Medicare payment rates for specified covered outpatient drugs "if hospital acquisition cost data are not available." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("subclause II"); *see* GAO-06-372, at 5 (describing the difficulties GAO encountered in conducting such surveys and finding that it "would not be practical for collecting the data needed to set and update . . . rates routinely"). Subclause II provides that, if "hospital cost acquisition data are not available," the payment amount shall be equal to "the average price for the drug in the year established under . . . section 1395w-3a of this title . . . as calculated and *adjusted by the*

Secretary as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added).

Under the provision that is cross-referenced in the alternative methodology, the starting point for the Medicare payment rate is generally 106% of a drug's average sales price. Because the average sales price reflects the price of the sale from the manufacturer to the provider, 106% of the average sales price is often an acceptable proxy for a hospital's acquisition cost plus overhead. *See, e.g.*, GAO-06-372, at 4; 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012); *see also* HHS Office of Inspector General, *Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System* 1, 3 (Oct. 22, 2010), https://go.usa.gov/xVg5Q (OEI-03-09-00420) (finding that for the selection of specified covered outpatient drugs it reviewed, Medicare payments were within one percent of the providers' reported acquisition costs). As discussed below, however, beginning in 2015 it became apparent that certain hospitals were routinely acquiring drugs at well below the average sales price. Thus, in the OPPS rules at issue here, HHS exercised its adjustment authority to bring Medicare's payment amount for those drugs in line with the average acquisition cost of those drugs.

II. Factual Background And The OPPS Rules At Issue Here

A. The Disparity Between Medicare Rates And Average Acquisition Cost For Drugs Acquired Under The 340B Program

This case involves the intersection of the Medicare program with a separate program known as the 340B program, which was established in 1992 by Section 340B of the Public Health Service Act. Section 340B requires drug manufacturers, as a condition of Medicaid participation, to sell drugs at discounted prices to providers known as "covered entities," including, for example, federally qualified health centers. Public Health Service Act, § 340B, 42 U.S.C. § 256b.

Under Section 340B, drug manufacturers must offer drugs to covered entities at or below a "maximum" or "ceiling price," which is calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1)-(2). In practice, hospitals and other covered entities have been able to negotiate significantly steeper discounts than the maximum statutory price. That is in part due to the fact that HHS's Health Resources and Services Administration operates the Prime Vendor Program through which covered entities may contract with a prime vendor to purchase covered drugs at deeper discounts. At the end of fiscal year 2015, the Prime Vendor Program made "nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the [already-discounted] 340B ceiling price." 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017).

In a 2015 report to Congress, the GAO found that "the amount of the 340B discount ranges from an estimated 20 to 50 percent off what the entity would have otherwise paid" to purchase the drug. GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* 8 (June 5, 2015) https://www.gao.gov/assets/680/670676.pdf (GAO-15-442). Similarly, in 2016, the Medicare Payment Advisory Commission reported that "the aggregate discount on Part B drugs received by covered entities equaled 33.6 percent of the average sales price (ASP) in 2013." Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* 79 (Mar. 15, 2016), https://go.usa.gov/xV2jj. And in November 2015, a report by the HHS Office of Inspector General found that Medicare payments were "58 percent more than [already-discounted] 340B ceiling prices [for 2013], which allowed covered entities to retain approximately $1.3 billion [in profit]." HHS Office of Inspector General, *Part B Payments for 340B-Purchased Drugs* Exec. Summ., (Nov. 2015), https://go.usa.gov/xV2jK (OEI-12-14-00030). Perhaps unsurprisingly, the number of hospitals participating in the 340B Program more than tripled between 2005 and 2014. *See* 82 Fed. Reg. at 52,495.

B. The 2018 And 2019 OPPS Rules

In its proposed rule setting OPPS rates for the 2018 year, HHS addressed the disparity identified in the reports of the GAO, the Medicare Payment Advisory Commission, and the HHS Office of Inspector General, which found wide discrepancies between the amounts that 340B program participants were paying for

covered outpatient drugs and the rate at which Medicare was reimbursing hospitals for those drugs. *See* 82 Fed. Reg. 33,558, 33,632-33 (July 20, 2017). In light of those findings, HHS made adjustments to the payment rate for 340B drugs that were designed to bring the Medicare payment amount in line with the average acquisition cost of these drugs. *See id.* at 33,633-34.[3]

The final rule for 2018 established a new sub-classification for drugs purchased by 340B providers, and it reduced the payment rate for such drugs "from average sales price (ASP) plus 6 percent to [average sales price] minus 22.5 percent." 82 Fed. Reg. at 52,362. HHS later established the same Medicare payment rate for the 2019 year. *See* 83 Fed. Reg. 58,818, 58,979-80 (Nov. 21, 2018).

In making this adjustment, HHS noted the rapid and substantial growth of Medicare spending for 340B drugs and the studies detailing that hospitals were able to purchase 340B drugs well below the statutory ceiling price. *See* 82 Fed. Reg. at 52,494-95. For example, in addition to the reports discussed above, HHS noted that a 2015 report of the Medicare Payment Advisory Commission estimated that "on average, hospitals in the 340B Program receive a *minimum discount of 22.5 percent* of the [average sales price] for drugs paid under the [OPPS]." *Id.* at 52,494 (second alteration in original) (emphasis added) (quotation marks omitted).

[3] For simplicity, we use the term "340B drugs" as a shorthand for specified covered outpatient drugs and biologicals that are acquired by 340B hospitals.

HHS explained that higher Medicare payment rates for 340B drugs result in higher drug costs for beneficiaries. 82 Fed. Reg. at 52,495. Under the Medicare statute, a beneficiary's 20% copayment is tied to the Medicare payment rate, rather than to the hospital's purchase price. *Id.* As a consequence, inflated Medicare payments lead to inflated copayments for beneficiaries. *Id.* The HHS Office of Inspector General report cited by HHS found that for 35 drugs out of 500 studied, the "difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug." *Id.* (alterations in original).

HHS also noted that "drug spending increases . . . are correlated with participation in the 340B Program" and "on average, beneficiaries at 340B . . . hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals." 82 Fed. Reg. at 52,494 (citing GAO-15-442, at 20). These "differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status." *Id.*

In determining that the Medicare payment rate for drugs acquired by 340B hospitals should be adjusted to average sales price minus 22.5%, HHS explained that the 22.5% figure represented the "lower bound" of the "minimum" average discount for 340B hospitals. 82 Fed. Reg. at 52,496. In other words, on average, the *minimum* discount hospitals are receiving is 22.5% below the average sales price. *Id.* In most

cases "the average discount is higher, potentially significantly higher, than . . . 22.5 percent." *Id.* HHS noted that "discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of [the average sales price], allowing these [340B] providers to generate significant profits when they administer Part B drugs." *Id.* at 52,494. The agency selected "the "conservative" figure of 22.5 percent, *id.* at 52,502, to ensure that 340B providers would not be reimbursed below their acquisition costs, *id.* at 52,497. The adjustment would thus "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," and thereby "allow the Medicare program and Medicare beneficiaries to pay less for drugs . . . that are purchased under the 340B Program," ensuring that beneficiaries "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." *Id.* at 52,495; *see also* 83 Fed. Reg. at 58,979 (proposing to retain 2018 payment rate for 2019 because it "better, and more accurately, reflect[s] the resources and acquisition costs that these hospitals incur").

HHS exempted from the adjustment rural sole community hospitals, children's hospitals, and prospective-payment-system-exempt cancer hospitals. The adjustment also does not apply to covered entities that are paid under a separate payment scheme outside OPPS, such as critical access hospitals. *See* 82 Fed. Reg. at 52,493-511.

Adjustments made under paragraph 14 are expressly subject to the OPPS requirement of budget neutrality. *See* 42 U.S.C. § 1395*l*(t)(14)(H). HHS estimated that, for 2018, the adjusted payment rate for drugs acquired under the 340B program

would reduce Medicare payments for such drugs by $1.6 billion. *See* 82 Fed. Reg. at 52,509. HHS directed that the $1.6 billion in savings be redistributed, resulting in a 3.2% increase in the Medicare payment rates for non-drug items and services for 2018. *See id.* at 52,623. HHS subsequently used the same previously increased Medicare payment rates for other items and services in 2019 to reflect the reduced payments for 340B drugs. *See* 83 Fed. Reg. at 58,975-77 (explaining that HHS would carry over the adjustment for 340B drugs from CY 2018 and its methodology).

III. Procedural Background

A. This Court's Initial Decision

Plaintiffs are three hospital associations and three member hospitals. In November 2017, before the new 2018 payment rate for 340B drugs went into effect, plaintiffs filed suit in district court under the Administrative Procedure Act. They alleged that, in the absence of survey data, HHS has no statutory authority to adjust Medicare payment rates for 340B drugs in order to bring the Medicare rates in line with hospitals' average acquisition costs.

The government moved to dismiss the complaint for lack of jurisdiction and, alternatively, failure to state a claim. With respect to jurisdiction, the government's primary argument was that the Medicare statute expressly precludes both administrative and judicial review of adjustments to OPPS payment rates. Alternatively, assuming that administrative and judicial review was not precluded, the government urged that plaintiffs could not proceed with a pre-enforcement challenge

and instead were required under 42 U.S.C. § 405(g), (h) to present a concrete claim for reimbursement to HHS after the new rates took effect. The government also argued that plaintiffs' challenge would fail on the merits if subject to judicial review.

The district court did not reach the government's primary jurisdictional argument. Instead, the court dismissed the complaint on the alternative ground that presentment of a reimbursement claim was required. This Court affirmed on the same ground, without reaching the government's argument that the Medicare statute precludes administrative and judicial review of HHS's adjustment of OPPS rates. *See American Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018).

B. The District Court's Subsequent Rulings

The three member hospitals subsequently presented concrete reimbursement claims for 2018, and renewed their statutory argument in that context. *See* Dkt. No. 2, Exs. I-R. HHS rejected the claims on the ground that the Medicare statute precludes administrative review of adjustments to OPPS payment rates. *See id.* Plaintiffs then filed this suit, alleging that the rate reduction for 340B drugs in the 2018 rule exceeds HHS's statutory authority.

In December 2018, the district court issued an opinion declaring that HHS's adjustment to the payment rate for 340B drugs was *ultra vires*, and therefore not subject to the Medicare statute's preclusion of review. *See American Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 78-79 (D.D.C. 2018) (stating that this Court would construe § (t)(12)(A) to "prevent[] 'review only of those 'other adjustments' that the Medicare

Act authorizes the Secretary to make'" (quoting *Amgen*, 357 F.3d at 112)); *see also* JA61-96. The court recognized that the Medicare statute requires HHS to base Medicare's payment rate on a drug's average acquisition cost, if hospital acquisition cost data are available. 348 F. Supp. 3d at 82. But the court interpreted the Medicare statute to prohibit HHS from making an adjustment to bring Medicare payment rates in line with average acquisition cost, if HHS does not have survey data gathered under subparagraph (D). *Id.* The court emphasized that subclause I of section 1395*l*(t)(14)(A)(iii) requires HHS to use average acquisition cost in setting the Medicare rate when survey data are available, and interpreted that mandate to impose an implied limitation on the adjustments authorized by subclause II of the same provision. *Id.* In the district court's view, HHS cannot make adjustments under subclause (II), which sets 106% of average sales price as the default Medicare rate and authorizes HHS to make adjustments to that rate as necessary for the purposes of paragraph 14, that are designed "to mimic the result of subsection (I)—by setting rates designed to approximate acquisition costs." *Id.* (emphasis omitted).

Recognizing that the relief sought by plaintiffs would likely be "highly disruptive," the district court ordered additional briefing on remedy. 348 F. Supp. 3d at 85-86. The court noted that in light of the OPPS budget-neutrality requirements, the "retroactive OPPS payments that [p]laintiffs seek here would presumably require similar offsets elsewhere; a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018." *Id.* at 86.

In May 2019, the district court issued an opinion that reiterated its conclusion that the rate reduction for 2018 was *ultra vires* and declared the 2019 payment rate to be *ultra vires* for the same reason. JA139-41.[4] The court acknowledged, however, that determining "how to 'unscramble the egg,' so to speak," is "no easy task, given Medicare's complexity." JA142. For example, the court noted that "if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services." JA148. "And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect." *Id.* (citing JA98-100 (¶¶ 5-9) (Richter Decl.) (providing HHS's estimate that recoupment would take a year, require between $25 million and $30 million in administrative costs, and adversely impact Medicare beneficiaries who would owe different amounts under their cost-sharing obligations)). The court also noted that the Federation of American Hospitals—which appeared as amicus on behalf of more than 1,000 non-340B hospitals—urged that HHS "lacks authority to recoup any or all of the 3.2[%] budget neutrality adjustment" made in the 2018 OPPS Rule. JA150 & n.20.

[4] Plaintiffs challenged the 2019 reduced rate for 340B drugs in a supplemental complaint filed after the 2019 rule took effect. *See* JA102-26.

The district court thus rejected plaintiffs' request that it simply order HHS to pay them the amounts they would have received in 2018 and 2019 if the payment rate for 2017 had been in effect for those years. JA142-43. Instead, the court remanded without vacatur, with instructions to HHS to devise a remedy. JA151. On July 10, 2019, the court entered final judgment, allowing for this appeal. JA152.

SUMMARY OF ARGUMENT

Each year, through notice-and-comment rulemaking, HHS sets the rates that Medicare Part B will pay providers for items and services during the upcoming calendar year. Pursuant to the Medicare statute, these rates are designed to approximate the costs incurred by efficient providers. The statute directs HHS to revise the rates each year to take into account new cost data, and empowers HHS to make adjustments as necessary to ensure equitable payments. *See* 42 U.S.C. § 1395*l*(t)(2)(E), (9)(A). The statute further mandates that rate adjustments be budget neutral, meaning that an increase in rates for particular items or services must be offset by a reduction in rates for other items or services. *See id.* § 1395*l*(t)(2)(E), (9)(B), (14)(H).

The downward rate adjustment at issue here brought the Medicare payment rate for certain drugs closer to being in line with their acquisition costs. That rate adjustment—which resulted in an increase in the Medicare rates for other items and services—was unquestionably within HHS's authority. The Medicare provision at issue here requires HHS to set the Medicare payment rate for the drugs at issue here

at their average acquisition costs, as informed by certain hospital survey data, where such data is available. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). And, in the absence of such survey data, that provision authorizes HHS to adjust the Medicare payment rate (106% of the drug's average sales price) for such drugs as necessary to achieve the provision's overarching purpose, which is to compensate providers for a drug's average acquisition cost. *Id.* § 1395*l*(t)(14)(A)(iii)(II).

No provider claimed during the rulemaking that the various reports on which HHS relied were inaccurate or that the adjusted Medicare rate would not compensate it for its costs. Contrary to the district court's understanding, the Medicare statute does not compel HHS to overpay for the drugs at issue here and thus underpay for other items and services—a result manifestly at odds with the Medicare statute's objective of providing equitable payments. The adjustment at issue here is reasonable and within HHS's authority, and, if reviewable, would properly be upheld under the standards of the APA. Plaintiffs clearly have not demonstrated the "patent violation of agency authority" that would constitute *ultra vires* action. *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016).

STANDARD OF REVIEW

The district court's decision rests on issues of law that are subject to de novo review in this Court. *See, e.g.*, *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 518 (D.C. Cir. 2016).

ARGUMENT

THE DISTRICT COURT ERRED IN DECLARING THAT HHS'S ADJUSTMENT TO MEDICARE RATES FOR 340B DRUGS EXCEEDS HHS'S AUTHORITY

A. The Medicare Statute Expressly Precludes Review Of OPPS Adjustments, Including Adjustments Under Paragraph 14.

The Department of Health & Human Services sets Medicare Part B payment rates for a given year through annual notice-and-comment rulemaking. To protect the Medicare trust fund, the Medicare statute generally requires that changes to Part B rates be budget neutral, which means that an increase in rates for particular services must be offset by a reduction in rates for other services. *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004); *see, e.g.*, 42 U.S.C. § 1395*l*(t)(2)(E), (t)(9)(B), (t)(14)(H).

Medicare payment rates are designed to approximate the costs incurred by efficient providers. The Medicare statute sets out various factors that provide the starting point for rates, and vests HHS with broad authority to make "other adjustments as determined to be necessary to ensure equitable payments." 42 U.S.C. § 1395*l*(t)(2)(E)). The statute further directs HHS not less often than annually to revise components of OPPS to take into account (*inter alia*) "new cost data." *Id.* § 1395*l*(t)(9)(A).

The Medicare statute expressly precludes administrative and judicial review of such adjustments (and other aspects of OPPS). *See* 42 U.S.C. § 1395*l*(t)(12)(A), (C). In *Amgen*, this Court found the Medicare statute's preclusion of review "unsurprising, for piecemeal review of individual payment determinations could frustrate the

efficient operation of the complex prospective payment system." 357 F.3d at 112. This Court noted that "[p]ayments to hospitals are made on a prospective basis, and given the length of time that review of individual payment determinations could take, review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year." *Id.* Moreover, this Court recognized that "equitable adjustments to payment rates are subject to a budget-neutrality requirement under § (t)(2)(E), such that judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year." *Id.*

Amgen qualified this reasoning by stating that it would interpret the Medicare statute "to prevent review only of those 'other adjustments' that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of 'other adjustments' extends no further than the Secretary's statutory authority to make them." *Amgen*, 357 F.3d at 112. However, this Court has never applied that qualification to invalidate any OPPS rate adjustment. In this Court's recent decision in *DCH Regional Medical Center v. Azar*, 925 F.3d 503 (D.C. Cir. 2019), the Court clarified that *ultra vires* review is permitted only when (1) "the statutory preclusion of review is implied rather than express;" and, (2) "the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory," *id.* at 509.

Neither condition is met here. The Medicare statute's preclusion of review is express, rather than implied. And as discussed below, the challenged rate adjustment achieved the statutory goal of providing payments that reflect a hospital's acquisition cost. The adjustment is reasonable and wholly consistent with the terms of the statute, and plaintiffs' challenge accordingly would fail even if the challenged rules were subject to review under the usual APA standards. Even more clearly, plaintiffs have not demonstrated the "patent violation of agency authority" that would constitute *ultra vires* action. *Florida Health Scis. Ctr., Inc. v. Secretary of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016); *see DCH Reg'l*, 925 F.3d at 509 (emphasizing that a claim of *ultra vires* action requires a showing of "extreme" agency error, not merely "[g]arden-variety errors of law or fact" (alteration in original)); *American Clinical Lab. Ass'n v. Azar*, 931 F.3d 1195, 1208 (D.C. Cir. 2019) (reiterating that *ultra vires* review is "of extremely limited scope, and it represents a more difficult course . . . than would review under the APA") (quotation marks omitted and ellipsis in original).

B. Congress Did Not Bar HHS From Making Adjustments That Align Medicare's Payment With Providers' Costs.

The overarching purpose of OPPS rates is to compensate efficient providers for their costs. Paragraph 14 thus requires HHS to use "average acquisition cost" as the Medicare payment amount for specified covered outpatient drugs, as informed by certain hospital survey data, where such data is available. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I). Paragraph 14 directed the GAO to conduct a survey in 2004

and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug, to furnish such data to the Secretary for use in setting payment rates, and to recommend to HHS the frequency and methodology of subsequent surveys. *Id.* § 1395*l*(t)(14)(D)(i)-(iii). Paragraph 14 provided that, beginning with the 2006 year, the Medicare payment amount for each specified covered outpatient drug shall be equal to the average acquisition cost for the drug for that year (which may vary by hospital group), as determined by HHS, taking into account the survey data. *Id.* § 1395*l*(t)(14)(A)(iii)(I).

Congress recognized that GAO might not recommend HHS gather survey data annually, and provided an alternative methodology for HHS to use in setting Medicare payment rates for specified covered outpatient drugs "if hospital cost acquisition data are not available." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The alternative methodology is designed to achieve the same result of covering the average acquisition cost for the specified covered outpatient drugs. The starting assumption of the alternative methodology is that the average sales price is generally a good proxy for hospital acquisition costs, and, as long as that assumption holds true, the Medicare payment rate is thus 106% of the average sales price, a figure that includes overhead costs. *See, e.g.*, GAO, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS* 4 (Apr. 2006), https://www.gao.gov/assets/250/249967.pdf (GAO-06-372); 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012); *see also* HHS Office of Inspector General, *Memorandum Report:*

Payment for Drugs Under the Hospital Outpatient Prospective Payment System, at 1 (Oct. 22, 2010), https://go.usa.gov/xVg5Q (OEI-03-09-00420) (finding that for the selection of specified covered outpatient drugs it reviewed, Medicare payments were within one percent of the providers' reported acquisition costs).

Congress did not, however, command use of the 106% figure regardless of evidence of hospitals' actual acquisition costs. Instead, the statute provides that, if survey data are not available, the Medicare payment amount for specified covered outpatient drugs shall be 106% of a drug's average sales price, as calculated and "adjusted by the Secretary as necessary for purposes of" paragraph 14. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

In November 2015, the HHS Office of Inspector General found that Medicare payments were 58 percent more than already-discounted 340B ceiling prices. *See* 82 Fed. Reg. at 52,495. That report noted that for 35 drugs out of 500 studied, "the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug" in at least one quarter of 2013. *Id.* (ellipsis in original). The GAO similarly found that the amount of the 340B discount ranges from 20 to 50 percent. *See* GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* 8 (June 5, 2015) https://www.gao.gov/assets/680/670676.pdf (GAO-15-442). And the Medicare Payment Advisory Commission found that the aggregate discount equaled 33.6 percent of average sales price. *See* Medicare Payment Advisory Commission, *Report to*

the Congress: Medicare Payment Policy 79 (Mar. 15, 2016), https://go.usa.gov/xV2jj; *see also* Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program* 7 (May 2015), https://go.usa.gov/xVgXN (estimating that 22.5% of average sales price represents the lower bound of the average discount for drugs purchased under the 340B program).

In light of these findings, HHS adjusted the Medicare payment amount for drugs acquired under the 340B program to average sales price minus 22.5%. In making that adjustment, HHS emphasized that the 22.5% figure represented the "lower bound" of the "minimum" average discount, which meant that, on average, the *minimum* discount hospitals are receiving is 22.5% below the average sales price. 82 Fed. Reg. at 52,496. Because in most cases, "the average discount is higher, potentially significantly higher, than . . . 22.5 percent," *id.*, the "conservative" figure, *id.* at 52,502, was selected to ensure that 340B providers would not be reimbursed below their acquisition costs, *id.* at 52,497.

HHS explained that higher Medicare payment rates for 340B drugs result in higher drug costs for beneficiaries. 82 Fed. Reg. at 52,495. Under the Medicare statute, a beneficiary's 20% copayment is tied to the Medicare payment rate, rather than to the hospital's purchase price. *Id.* As a consequence, inflated Medicare payments lead to inflated copayments for beneficiaries. *Id.*

HHS further explained that the adjusted Medicare payment was supported by a number of commenters, including organizations representing physician oncology

practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and several individual Medicare beneficiaries. *See* 82 Fed. Reg. at 52,497. One commenter stated that the proposal would reduce drug costs for seniors by an estimated $180 million a year. *See id.* Another noted such cost-sharing savings are particularly significant for cancer patients, for whom drug cost is an important component of overall outpatient costs. *See id.*

HHS also addressed criticism of the proposed adjustment from commenters representing 340B providers, who stated that the reduced Medicare payment would greatly "undermine 340B hospitals' ability to continue programs designed to improve access to services—the very goal of the 340B Program." 82 Fed. Reg. at 52,498. The agency noted that it had received no comments suggesting that a figure other than average sales price minus 22.5% would better reflect the hospital acquisition costs for drugs acquired by 340B providers. *Id.* at 52,500 (noting, for example, that no commenter proposed average sales price minus 17% instead). That omission was "notable because hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPS payment rates for drugs." *Id.* HHS explained that the failure of any affected hospital to object to the specific figure gave HHS confidence that the rate "is, in fact, the low bound of the estimate and keeps Medicare payment within the range where hospitals will not be underpaid for their acquisition costs of such drugs." *Id.* HHS rejected the contention that it is appropriate for the Medicare

program to subsidize 340B providers by paying them more than their average acquisition costs for specified covered outpatient drugs. *Id.* at 52,495.

C. The District Court's *Ultra Vires* Ruling Rests On A Misunderstanding Of Paragraph 14.

The district court gave no sound reason for declaring the adjusted Medicare rate for drugs acquired by 340B providers to be *ultra vires*. The court did not suggest that Congress intended that the Medicare program should subsidize 340B providers by paying inflated amounts. Nor did the court dispute that the adjusted Medicare rate of average sales price minus 22.5% is a conservative estimate of the discount that 340B providers receive for specified covered outpatient drugs. As discussed above, there is ample support for that conclusion in the administrative record, and no 340B hospital argued during the rulemakings that the figure overstated the discount 340B hospitals receive.

The district court wrongly inferred from subclause I—which *requires* HHS to base the Medicare payment amount on average acquisition cost, as informed by survey data when such data are available—that Congress intended to *prohibit* HHS from taking information about acquisition cost into account unless HHS collects such data through a survey. The central purpose of paragraph 14 is to compensate hospitals for the average acquisition cost of specified covered outpatient drugs. That is why paragraph 14 requires HHS to use average acquisition cost as the basis for the Medicare payment when survey data are available. The assumption underlying the

alternative methodology for establishing the payment rate is that average sales price will closely mirror hospitals' acquisition costs.

But Congress did not preclude the agency from taking action when that assumption proves false. The Medicare statute specifically directs HHS to revise OPPS rates each year to take into account "new cost data," 42 U.S.C. § 1395*l*(t)(9)(A), and empowers HHS to make "adjustments as determined to be necessary to ensure equitable payments," *id.* § 1395*l*(t)(2)(E). And subclause II in particular gives HHS broad authority to adjust the starting point for the Medicare payment amount for specified covered outpatient drugs (106% of average sales price) "as necessary for purposes of" paragraph 14. *Id.* § 1395*l*(t)(14)(A)(iii)(II). The manifest purpose of paragraph 14 is to compensate providers for the average acquisition cost of specified covered outpatient drugs. The district court did not conclude otherwise or identify any other purpose that paragraph 14 is intended to serve.

Consideration of new cost data helps to ensure that Medicare payments are equitable, which is especially important because the Medicare payment amounts established under paragraph 14 are subject to the requirement of budget neutrality. *See* 42 U.S.C. § 1395*l*(t)(14)(H). Thus, overcompensation for some drugs or treatments means reduced payments for other drugs and treatments, and correcting overcompensation permits more equitable distribution of limited funds. The result of bringing the Medicare payment amount for 340B drugs into alignment with average acquisition cost was therefore the redistribution of the anticipated $1.6 billion in

savings, resulting in a 3.2% increase in the Medicare payment rates for non-drug items and services. *See* 82 Fed. Reg. at 52,623. That is a quintessential exercise of HHS's authority to make adjustments as necessary to make Medicare payments equitable.

The district court's contrary reasoning replicated the type of *expressio unius* argument that this Court rejected in a case involving adjustments to Medicare rates under the inpatient prospective payment system. In *Adirondack Medical Center v. Sebelius*, 740 F.3d 692 (D.C. Cir. 2014), the aggrieved hospitals argued that a provision authorizing HHS to "adjust the average standardized amounts" meant that HHS could "adjust *only* the standardized amounts" and impliedly precluded HHS from using other adjustment authority to make changes to the same rates, *id.* at 697. Rejecting that argument, the Court noted that "Congress generally knows how to use the word 'only' when drafting laws," *id.*, and emphasized that the "*expressio unius* canon is a 'feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved.'" *Id.* "And when countervailed by a broad grant of authority contained within the same statutory scheme, the canon is a poor indicator of Congress'[s] intent." *Id.*

Here, as in *Adirondack*, the plaintiff hospitals assert that by requiring HHS to use average acquisition cost as the Medicare payment amount when survey data are available (under subclause I), Congress impliedly precluded HHS from taking acquisition cost data into account when making rate adjustments in the absence of survey data (under subclause II). Here, as in *Adirondack*, the argument fails.

Subclause I does not include the word "only." It does not limit the authority in subclause II to adjust the Medicare payment amount as necessary for the purposes of paragraph 14. Nor does it limit HHS's broad authority to make "adjustments [to OPPS rates] as determined to be necessary to ensure equitable payments," 42 U.S.C. § 1395*l*(t)(2)(E), and to periodically adjust OPPS rates in light of "new cost data," *id.* § 1395*l*(t)(9)(A).

The district court was likewise wrong to declare that HHS's change in the Medicare payment amount for 340B drugs is not an "adjustment" within the meaning of the statute because the change was "not modest" and potentially affects a large number of drugs. *American Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 81 (D.D.C. 2018). Because HHS may adjust the Medicare payment amount to align it with average acquisition costs, the size of the adjustment properly reflects the size of the disparity between the Medicare rate and the acquisition costs. The adjusted rate is a conservative estimate of the discount at which 340B providers acquire specified covered outpatient drugs, and the 340B providers did not contend otherwise during the rulemakings. Nothing in the Medicare statute's text, structure, or purpose suggests that HHS may only make small adjustments under subclause II, when faced

with a large disparity between Medicare payments and acquisition costs for 340B drugs.[5]

The district court's pronouncement that HHS "fundamentally altered the statutory scheme established by Congress for determining [specified covered outpatient drug] reimbursement rates," 348 F. Supp. 3d at 81, rests on the mistaken premise that Congress intended that Medicare make inflated payments to 340B providers at the expense of other providers and beneficiaries. Neither plaintiffs nor the district court identified any "purposes" of paragraph 14 other than to ensure that Medicare payments approximate acquisition costs. But on the district court's reasoning, the Secretary would have the authority to adjust such payments only when the statutory proxy for acquisition costs was close to actual acquisition cost. If, as is the case for 340B providers, the overpayment is substantial, the Secretary would lack authority to address the inequity. That premise finds no support in the text or

[5] Numerous dictionaries define "adjust" without using the word "slight" or any other term that could be construed to impose a quantitative limitation. *See, e.g.*, *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust ("a: to bring to a more satisfactory state . . . b: to make correspondent or conformable . . . c: to bring the parts of to a true or more effective relative position"); *Adjust*, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=adjust ("1.a. To move or change (something) so as to be in a more effective arrangement or desired condition . . . b. To change so as to be suitable to or conform with something else"); *Adjust*, Random House Dictionary, http://www.dictionary.com/browse/adjust ("1. to change (something) so that it fits, corresponds, or conforms; adapt; accommodate . . . 2. to put in good working order; regulate; bring to a proper state or position"); *Adjust*, Black's Law Dictionary Free (2d ed.), https://thelawdictionary.org/adjust/ ("To bring to proper relations; to settle; to determine and apportion an amount due.").

purpose of paragraph 14, and it is fundamentally at odds with the core OPPS objective of establishing equitable Medicare rates that approximate the costs incurred by efficient providers.

D. The Difficulty Of Devising An Appropriate Remedy Underscores Why Congress Precluded Judicial Review Of OPPS Adjustments.

Although it is unnecessary to reach the issue because the challenged rate adjustment is within HHS's authority, the difficulty of devising an appropriate remedy underscores why the Medicare statute expressly precludes judicial review of OPPS adjustments and other aspects of the outpatient prospective payment system.

For the 2018 year alone, HHS expected to process more than 110 million OPPS claims. JA98-99 (¶¶ 3, 7) (Richter Decl.). With considerable understatement, the district court acknowledged that determining "how to 'unscramble the egg,' so to speak," is "no easy task, given Medicare's complexity." JA142. Because OPPS rates are budget neutral, the downward adjustment to the payment rate for the drugs at issue here resulted in a 3.2% increase in the Medicare payment rates for non-drug items and services. 82 Fed. Reg. at 52,623. The district court thus recognized that the "retroactive OPPS payments that [p]laintiffs seek here would presumably require similar offsets elsewhere; a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018." 348 F. Supp. 3d at 86.

In light of the district court's remand order, HHS recently solicited public comment on remedial options that could be considered if the district court's ruling

were upheld. *See* 84 Fed. Reg. 39,398, 39,504-05 (Aug. 9, 2019). HHS noted that any change to the payment rate for 340B hospitals could have a significant economic impact on the approximately 3,900 facilities that are reimbursed for outpatient items and services covered under the OPPS. *Id.* at 39,504. Furthermore, HHS explained that any remedy could have a significant effect on the cost sharing owed by Medicare beneficiaries, which, by statute, is typically 20 percent of the Medicare payment rate. *Id.* HHS anticipated that balancing "the statutory budget neutrality requirement and beneficiary cost-sharing" would be "extremely difficult." *Id.* at 39,505.

In *Amgen*, this Court interpreted the Medicare statute's categorical prohibition on judicial review of OPPS adjustments to leave room for *ultra vires* review. This Court reasoned that "the interference with the administration of the Medicare B program that would result from judicial review pertaining to the overall scope of the Secretary's statutory adjustment authority" would "be sufficiently offset by the likely gains from reducing the risk of systematic misinterpretation in the administration of the Medicare B program." 357 F.3d at 113. This Court has never applied that reasoning to invalidate an OPPS adjustment, however, and this case calls into question the assumption that the benefits of judicial review would outweigh the harm from disruption.

Nor is there an evident need for judicial oversight of OPPS rates, because Congress regularly intervenes to revise the OPPS provisions. For example, in October 2018, Congress amended § 1395*l*(t) to add a new paragraph addressing the

payment rates for opioids. *See* Pub. L. No. 115-271, § 6082, 132 Stat. 3992, 3992-93 (Oct. 24, 2018) (amending § 1395*l*(t) to add paragraph 22). By contrast, Congress did not amend paragraph 14, even though HHS had already established the reduced rate for 340B drugs for the 2018 year and announced its proposal to do the same for 2019. Under these circumstances, a court should be particularly hesitant to unravel rates that Congress did not choose to amend. More generally, Congress's regular refinement of the OPPS provisions refutes the suggestion that intervention by the courts is needed to prevent "systematic misinterpretation in the administration of the Medicare B program." *Amgen*, 357 F.3d at 113.

CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8,774 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Laura E. Myron
LAURA E. MYRON

CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Laura E. Myron
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ADDENDUM

TABLE OF CONTENTS

42 U.S.C. § 1395*l*(t) Prospective Payment System for Hospital Outpatient Department Services

(2) System Requirements Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not;

. . . .

(9) Periodic Review and Adjustments Components of Prospective Payment System

(A) Periodic Review—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other

adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget Neutrality Adjustment—If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. . . .

(C) Update Factor—If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(12) Limitation on Review—There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the Medicare OPD fee schedule amount associated with particular

devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(14) Drug APC Payment Rates

(A) In general – The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(*o*) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for the purposes of this paragraph.

(B) Specified Covered Outpatient Drug Defined

(i) **In general** – In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in section 1396r-8(k) of this title) for which a separate ambulatory payment classification group (APC) has been established and that is

(I) a radio pharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) **Exception** – Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) Payment for designated orphan drugs during 2004 and 2005

The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) Acquisition cost survey for hospital outpatient drugs

(i) **Annual GAO surveys in 2004 and 2005**

(I) **In general**—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) **Recommendations**—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) **Subsequent secretarial surveys**—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) **Survey requirements**—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) **Differentiation in cost**—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) **Comment on proposed rates**—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) Adjustment in payment rates for overhead costs

(i) **MedPAC Report on Drug APC Design**- The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(vi) **Adjustment authorized** - The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i)

(F) Classes of drugs

For purposes of this paragraph:

(i) **Sole source drugs**—The term "sole source drug" means—

(I) a biological product (as defined under section 1395x(t)(1) of this title); or

(II) a single source drug (as defined in section 1396r–8(k)(7)(A)(iv) of this title).

(ii) **Innovator multiple source drugs**—The term "innovator multiple source drug" has the meaning given such term in section 1396r–8(k)(7)(A)(ii) of this title.

(iii) **Noninnovator multiple source drugs**—The term "noninnovator multiple source drug" has the meaning given such term in section 1396r–8(k)(7)(A)(iii) of this title.

(G) Reference average wholesale price

The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1395u(o) of this title as of May 1, 2003.

(H) Inapplicability of expenditures in determining conversion, weighting, and other adjustment factors

Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.