IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN ASSOCIATION OF ANCILLARY BENEFITS, A FLORIDA NOT-FOR-PROFIT CORPORATION,	§	
Plaintiff,	§	Case No. 24-CV-783
v.	§	**Honorable Judge Sean D. Jordan**
XAVIER BECERRA, in his official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, JULIE A. SU, in her official capacity, as acting UNITED STATES SECRETARY OF LABOR, and JANET YELLEN, in her official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF THE TREASURY,	§	
Defendants.	§	

PLAINTIFF'S MOTION FOR LEAVE TO FILE BRIEF IN EXCESS OF PAGE LIMITATION REQUIREMENTS

NOW COMES Plaintiff, AMERICAN ASSOCIATION OF ANCILLARY BENEFITS, A FLORIDA NOT-FOR-PROFIT CORPORATION, by and through its attorneys, Gonzales Taplin, P.A. and Peterson, Johnson and Murray LLC, and for their Motion for Leave to file a brief in excess of page limitation requirements, states as follows:

1. Local Rule CV-7k limits briefs to 15 pages.
2. Plaintiff has prepared a Memorandum of Law in Support of Its Emergency Motion for a Temporary Restraining Order, Stay of effective Date and Preliminary Injunction that is 26 pages in length.

3. The length of the brief was directly due to the nature of the Memorandum of Law and the multiple legal issues therein to support its prayer for injunctive relief.
4. Plaintiff does not believe that any party to this matter would be prejudiced by the granting of this motion.

WHEREFORE, Plaintiff, AMERICAN ASSOCIATION OF ANCILLARY BENEFITS, A FLORIDA NOT-FOR-PROFIT CORPORATION, prays that this Honorable Court enters an Order granting this motion, and for any further relief this Court deems fair and just.

Respectfully submitted,

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CERTIFICATION OF CONFERENCE

I, Dominick L. Lanzito, hereby certify that on August 28, 2024, one of the attorneys for Plaintiff, attempted to confer with one of the attorneys for one of the Defendants (HHS) regarding the intent to file the motion for Injunctive Relief and Memorandum of Law; however, the parties were not able to confer telephonically, prior to filing of this motion. As such there is no agreement reached between the parties concerning Plaintiff's Motion for Leave to file a brief in excess of page limitation requirements.

Dated August 29, 2024

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
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Plaintiff,	§	Case No. 24-CV-783
v.	§	Judge Sean D. Jordan
XAVIER BECERRA, in his official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, JULIE A. SU, in her official capacity, as acting UNITED STATES SECRETARY OF LABOR, and JANET YELLEN, in her official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF THE TREASURY,	§	
Defendants.	§	

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT ITS EMERGENCY MOTION FOR A TEMPORARY RESTRAINING ORDER, STAY OF EFFECTIVE DATE AND PRELIMINARY INJUNCTION

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Plaintiff, AMERICAN ASSOCIATION OF ANCILLARY BENEFITS, a Florida not-for-profit corporation ("AAAB" or "Plaintiff"), by and through its attorneys, Gonzales Taplin, P.A. and Peterson, Johnson and Murray LLC, and for Plaintiff's Memorandum of Law in support of its Emergency Motion for a Temporary Restraining Order, Stay of Effective Date, and Preliminary Injunction related to the new Rule for Short-Term, Limited Duration Insurance Plans promulgated by XAVIER BECERRA, in his official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JULIE A. SU, in her official capacity, as acting UNITED STATES SECRETARY OF LABOR; and JANET YELLEN, in her official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF THE TREASURY, (individually referred to respectively as "CMS", "DOL" or "TREASURY" and collectively referred to as "Defendants"), states as follows:

EMERGENCY REQUEST FOR EXPEDITION:

As detailed in AAAB's concurrently filed motion to expedite, Plaintiff respectfully requests that the Court shorten the briefing schedule on AAAB's Motion for a Temporary Restraining Order, Stay of Effective Date and Preliminary Injunction. Expedition is necessary, and proceeding under Local Rule CV-7(e) inadequate, in order to avoid immediate and irreparable injury to AAAB, its association members, and countless other employers as their business operations will be massively and needlessly disrupted by the loss of vital revenue from the sale of STLDI plans. Also, hundreds of thousands of policy holders nationwide will suffer immediate and irreparable harm from becoming uninsured.

INTRODUCTION:

Consistent with the recent history of this Administration's (and its agencies') impermissible attempts to legislate by Executive Order and Administrative Rules[1], Defendants have promulgated Rule CMS-9904-F (the "New Rule") (89 Fed. Reg. 23338 (April 3, 2024) / CMS-9904-F attached hereto as Exhibit 1), which is scheduled to become effective on September 1, 2024. The New Rule takes aim at Short-Term, Limited Duration Insurance ("STLDI").

Without Congressional action, Defendants have limited the term and duration of STLDIs in such a manner that renders those plans functionally useless. The New Rule's intent is to force consumers to choose Affordable Care Act ("ACA") insurance plans by eliminating the practical use of STLDI plans. The catalyst for the New Rule was President Biden's Executive Order 14009, executed on January 28, 2021, which sought revocation of Former President Trump's Executive Order, entitled Promoting Healthcare Choice and Competition Across the United States. *See* Exec. Order 13813. Executive Order 13813 stated, in pertinent part,

> (ii) STLDI is exempt from the onerous and expensive insurance mandates and regulations included in title I of the PPACA. This can make it an appealing and affordable alternative to government-run exchanges for many people without coverage available to them through their workplaces. The previous administration took steps to restrict access to this market by reducing the allowable coverage period from less than 12 months to less than 3 months and by preventing any extensions selected by the policyholder beyond 3 months of total coverage.

See Exec. Order 13813, Sect. 1(b)(i).

The prior Executive Order also noted,

> The PPACA[2] has also largely failed to provide meaningful choice or competition between insurers, resulting in one-third of America's counties

[1] See, *Biden, President of the United States, et al. v. Nebraska, et al.,* 600 U.S. 477, 143 S. Ct. 2355 (holding that Secretary of Education's student loan forgiveness plan was invalid and an unauthorized attempt to rewrite a statute). See also, *Ryan, LLC v. Federal Trade Commission*, 24-cv-9896, Dkt. No. 211 (N.D. Texas) (enjoining Defendant FTC's Administrative Rule banning non-competition agreements and granting summary judgment in favor of Plaintiff.
[2] The PPACA stands for Patient Protection and Affordable Care Act but will be referred to herein as the "ACA."

> having only one insurer offering coverage on their applicable government-run exchange in 2017.

On July 12, 2024, years after President Biden's Executive Order, Defendants proposed and approved CMS-9904-F with an effective date of September 1, 2024. Curiously, Defendants believe they have the authority to take this momentous step because provisions of Sections 2701 through 2728 of the Public Health Service ("PHS") Act that authorizes *procedural* rules purportedly also authorizes a sweeping substantive regulation restricting STLDI plans.

The New Rule's change in STLDI plan duration has removed an option for insurance coverage from the market. *See* Exhibit 3, 83 Fed. Reg. 38212 at 38214 - 38215 (August 3, 2018). It will leave hundreds of thousands without access health coverage, will harm small businesses, and will remove competition from the insurance market. As a result, CMS 9904-F violates the Constitution, is procedurally and substantively deficient, and is arbitrary, capricious, and unlawful under the Administrative Procedure Act ("APA") and Regulatory Flexibility Act ("RFA").

This immensely disruptive New Rule should be stayed and prevented from taking effect during the pendency of this litigation. Irrespective of the goals of this impatient agency diktat, Defendants must operate exclusively within the authority granted to them by Congress. Allowing the New Rule to go into effect only to later vacate it would cause irreparable harm in the form of the loss of insurance coverage during dire times. Even if the New Rule were to be later countermanded, not only would the market have become already strained by erratic accommodation and reversion, but also hundreds of thousands of consumers will have needlessly suffered. AAAB, therefore, seeks an immediate stay of the effective date for Defendants' changes and a preliminary injunction against their enforcement.

BACKGROUND:[3]

Congress has recognized STLDI plans for decades. Pursuant to the PHS Act, "[t]he term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, *but does not include short-term, limited-duration insurance*." *See* 42 U.S.C. § 300gg-91(b)(5) (emphasis added). STLDI plans are a type of health plan designed to help provide short-term coverage as a flexible stopgap measure for individuals who need coverage for a short duration during transition of various life changes—such as job loss, waiting for other insurance coverage to begin, or transitioning between plans.

STLDI serves as a vital lifeline for individuals navigating transitions between ACA or employer sponsored plans, offering temporary healthcare coverage during periods of change (*See* Declaration of Michelle Delany, attached hereto as Exhibit 2, ¶8). STLDI plans provide crucial assistance for those encountering scenarios such as missing open enrollment periods or facing unexpected life events resulting in coverage gaps exceeding four months. *Id.* But Defendants' New Rule eliminates the elasticity necessary in administering STLDI plans and eliminates a product that competes with comprehensive ACA plans. To be clear, Plaintiff is not arguing that STLDI plans provide the same benefits or coverage as a comprehensive ACA plan. For some members of the public, however, it is either a personal choice to obtain STLDI plans or an absolute necessity to secure an STLDI plan to avoid gaps in health coverage. But regardless of the reason, the New Rule harms the health insurance industry and members of the public by limiting choices for health insurance. It also usurps the ability of State regulators to regulate the business of insurance as set forth in the McCarran-Ferguson Act.

[3] The facts set forth in this Memorandum include facts which are taken from the public record, which this Court can take judicial notice of; facts set forth in the Complaint, which are incorporated herein; and facts supported by the accompanying declaration. *See Boudreaux v. Louisiana State Bar Ass'n*, 86 F.4th 620, 635, n.12 (5th Cir. 2023) (noting judicial notice may be taken of public records and a government agency's website).

Defendants' New Rule seeks to restrict STLDI plans to a strict three-month term with one renewal for a total of four months of coverage. Conversely, the earlier Rule allowed the STDI plans to be renewed for a total of 36 months. Defendants' New Rule impermissibly rewrites legislation and transcends each Defendant's respective statutory authority. Under these circumstances, Defendants cannot promulgate substantive rules re-writing the definition of STLDI plans.

Even if Congress did, in fact, grant Defendants authority to promulgate some changes, it did not invest Defendants with unfettered authority to sweepingly decide major policy questions regarding STLDI plan duration—questions that have seismic consequences that affect millions of potentially uninsured persons, and billions of dollars in economic productivity. Indeed, Congress could not constitutionally have conferred this authority upon Defendants with the open-ended language the Defendants employed.

I. AAAB and STLDI plans

AAAB is a nonprofit trade association that services the ancillary benefits industry. Corrected Complaint at ¶ 7 (hereinafter Comp. at ¶#), Doc. No. 2.[4] AAAB advocates for the ancillary benefits industry on behalf of carriers, vendors, third parties, and distributors, as well as for specialty carriers, prepaid legal services, and other niche products in the insurance business segment. *Id.* AAAB members are industry leaders providing STLDI plans. *Id.* AAAB members are located throughout the country, including in the State of Texas. *Id.* AAAB routinely conducts business in Texas, including hosting educational and regulatory seminars for its members. *Id.*

There are well over 200,000 STLDI plans written through AAAB's 15 association members (*See* Ex. 2, Dec. Delany, ¶9). AAAB Association members work with and provide the

[4] The *Correct* Complaint and exhibits thereto are incorporated by reference herein.

STLDI plans and the platforms on which those products are sold to the consumer. *Id*. There are approximately 1,000 agents and brokers who market and sell the STLDI plans for and through the AAAB's association membership. *Id*. at ¶10.

STLDI Plans, marketed by and sold through AAAB membership, serve a key role—providing a vehicle/product for consumers to obtain health coverage for periods when they would otherwise have a coverage gap, such as leaving one place of employment for another. Comp. at ¶7. STLDI and FII Plans also provide consumers with a less expensive option to ACA plans and allow the public to select a plan that may suit their immediate personal and financial needs. *Id.*

Plaintiff does not argue that STLDI plans provide the same coverage as a traditional ACA Plan. Comp. at ¶20. But the Plans do afford consumers options that are tailored to their needs. *Id.* STLDI plans do not have any enrollment periods, so a consumer is critically able to obtain these plans regardless of the time of the year. *Id.* at ¶¶6, 18, 21, 23.

The benefits of STLDI plans for the consumer were judicially recognized in *Assoc. for Community Affiliated Plans v. U. S. Dept. of Treasury*, 392 F. Supp. 3d 22, 37 (D.C. Dist. Ct. July 18, 2019), *aff'd* 966 F.3d 782 (D.C. Cir. 2020). Comp. at ¶22. In that case, the United States Court for the D.C. Circuit Court of Appeals had affirmed the District Court opinions, which recognized that STLDI's presence in the marketplace would promote competition with ACA marketplaces and could ultimately reduce premiums to compete with other products. *Assoc. for Community Affiliated Plans v*, 392 F. Supp. 3d at 37. Similarly, in *Ketayi v. Health Enrollment Grp.*, No. 20-CV-1198-RSH-KSC, 2023 WL 6373071, at *17 (S.D. Cal. Sept. 14, 2023), the District Court acknowledged that limited benefit plans provide a more affordable option of health insurance, allow consumers to avoid stop-gap coverage outside of an ACA enrollment period, and could serve as a supplemental source of health benefits.

Although Defendants baselessly assert that STLDI plans are problematic because they cause consumer confusion, Congress has recognized STLDI plans for decades. Comp. at ¶97. *See Assoc. for Community Affiliated Plans,* 392 F. Supp. 3d, at 15. Pursuant to the PHS Act, "[t]he term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, *but does not include short-term, limited-duration insurance*." Comp. at ¶14. *See* 42 U.S.C. § 300gg-91(b)(5) (emphasis added). STLDI has been excepted from individual market regulations since the passage of the Health Insurance Portability and Accountability Act of 1996 (*See* Pub. L. No. 104-191, 110 Stat. 1936), which protects STLDI from individual market regulations. *Id.* at 15.

There can be no dispute that the New Rule determined that STLDI plans have "an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total." *See* Ex. 1, 89 Fed. Reg. 23338 at 23413 (April 3, 2024) *codified at* 29 CFR § 2590.701-2; Comp. at ¶16. But nowhere in any statutory authority is there a prohibition against purchasing an additional, different STLDI plan after the expiration of the prior STLDI plan. *Id.* at ¶58. That is a process that has been referred to as "stacking." *Id.*

The 2018 Rule allows for multiple renewals of STLDI plans for up to 36 months. *See* Ex. 3, 83 Fed. Reg. 38212 (Aug. 3, 2018); Comp. at ¶28. Given the obvious disdain for STLDI plans by the current administration—and with the intention to eradicate all competition with ACA health plans—Defendants promulgated their New Rule limiting STLDI plans to three months with only one renewal for a total duration of the plan for four months. *Id.* at ¶¶4, 22, 25, 80. But contrary to Defendants' New Rule, the PHS Act and similar statutory authority do not apply a time limit for

either the term or duration of STLDI plans. *Id.* at ¶17. Under the 2018 Rule, STLDI denotes health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract. *Id.* This construction was deemed consistent with the STLDI plan definition—offering consumers genuine choices when it came to their health insurance needs. *Id.* at ¶¶4, 6, 20, 22.

II. 2018 Rule related to STLDI plans.

In the eleventh hour of the current Administration, Defendants have turned the rule making process related to STLDI plans into a political football that will change any time that there is a change in administration. *Id.* at ¶26. By way of background, on August 3, 2018, these same Departments, under a prior administration, promulgated the current 2018 Rule related to the duration and number of renewals that could be obtained by a consumer for STLDI plans. *Id.* at ¶27 (*See* 83 Fed. Reg. 38212/CMS-9924-F). That Rule became effective October 2, 2018, and as previously stated, withstood judicial scrutiny. *Id.* at ¶27.

The 2018 Rule defined STLDI as

> health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total.

See 83 Fed. Reg. at 38212, 38214 - 38215.

The 2018 Rule extended the STLDI initial term to less than 12 months, which ultimately

> (1) helped individuals more easily maintain an uninterrupted period of prior "creditable coverage" to become eligible for the law's protections (and avoid the "significant break in coverage" that could negate eligibility), and (2) in some cases, reduced the period during which a new issuer could refuse benefits to a participant relating to preexisting conditions

Community Affiliated Plans, 392 F. Supp. 3d at 37.

The 2018 Rule has been in place for nearly six years, without issue. Comp. at ¶ 30. Indeed, prior to embarking on the promulgation of their New Rule, Defendants did not cite any specific direct evidence, rampant fraud, or any inability of the States to regulate STLDI plans. *Id.* Instead, they promulgated a Rule to cure a nonexistent illness.

It became clear that the New Rule only manifested after multiple failed attempts by Congress to legislate to override or invalidate both the current 2018 Rule and the D.C. Circuit ruling that validated the 2018 Rule. *Id.* at ¶31. *See Community Affiliated Plans*, 966 F.3d 782. There were six separate proposed bills between the U.S. House of Representatives and Senate, respectively to modify STLDI or invalidate the 2018 Rule—all of which ultimately failed, largely along party lines, between 2019 and 2021. *Id.* at ¶32. *See, e.g.* (Proposed Legislation, attached hereto as Group Exhibit 4: H.R. 987, 116th Congress (2019); S. 1556, 116th Congress (2019); H.R. 1010, 116th Congress (2019), H.R. 1425, 116th Congress (2019); S. 352, 117th Congress (2021); S. 942, 117th Congress (2021)). In addition, one bill designed to eliminate STLDI altogether failed in the 2021-2022 session. *See* H.R. 1875, 117th Congress (2021). These multiple failed attempts to modify/eliminate STLDI plans and override the 2018 Rule demonstrates that it would take an "Act" of Congress, via passed legislation, to significantly modify the 2018 Rule or eliminate STLDI plans from the health insurance marketplace. Comp. at ¶ 33.

a. Defendants' New Rule

After these multiple failed attempts to legislate changes to STLDI plans, Defendants published the 2024 New Rule on July 12, 2023. *Id.* at ¶ 34. Ex. 1, 89 Fed. Reg. 23338. Their New Rule also included regulatory amendments covering FII Plans, which are not at issue in this Motion. Nonetheless, the New Rule was advanced on a patently false narrative. According to the

text of the New Rule, "[t]he provisions finalized in these final rules will help ensure that consumers can better understand and properly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage, and access resources to learn more about their health coverage options." Comp. at ¶ 35 (Ex. 1, 89 Fed. Reg. 23338 (April 3, 2024)).

The New Rule further maintains that one of its "benefits" is that the changes are "expected to reduce the harm caused to consumers who are misled into enrolling in STLDI or fixed indemnity excepted benefits coverage as an alternative to or replacement for comprehensive coverage." Comp. at ¶ 36 (*See* Ex. 1, 89 Fed. Reg. 23338 at 23339 (April 3, 2024). But rather than requiring additional disclosures or notices to alleviate any consumer confusion, the New Rule eliminates consumer choice by impermissibly rendering STLDI plans functionally useless and putting consumers at risk of gaps in coverage. Comp. at ¶37. The New Rule does not even attempt to cloak its true purpose. *Id.* at ¶ 38. Rather, the very next sentence in the New Rule states, "[*t*]*hese final rules will encourage enrollment in comprehensive coverage* and lower the risk that STLDI and fixed indemnity excepted benefits coverage are viewed or marketed as a substitute for comprehensive coverage." *Id.* (*See* Ex. 1, 89 Fed. Reg. 23338 at 23393 (April 3, 2024) (emphasis added). The New Rule points to no empirical evidence showing that consumers were confused as to the nature of STLDI Plans, and it does not demonstrate concern of State insurance regulators who have the duty to address any inappropriate marketing of these products. *Id.* at ¶97. Thus, to accomplish their end goal of eliminating a product that may be selected by consumers in lieu of an ACA product, Defendants circumvented or paid short shrift to rulemaking requirements of both the APA and the RFA. *Id.* at ¶¶ 41-53, 87, 91, 101.

i. Rule making process.

5 U.S.C. § 553(b) sets forth the Defendants' pertinent rule-making responsibilities, which include that general notice of any proposed rulemaking is to be published in the Federal Register, and which—unless an exception applies—must include: the time, place, and nature of rulemaking proceedings; underlying legal authority; terms of the proposed rule; and an online link to a brief plain language version. *Id.* The agency also must give interested persons an opportunity to participate in such rulemaking. *Id.* at (c). Each agency is generally granted the authority to comply with those responsibilities. 5 U.S.C. § 559.

The administrative rule making process requires administrative agencies to accept and address concerns submitted via public comment. In this instance, Defendants received comments from Plaintiff, industry leaders, and even state regulators. Comp. ¶¶39-40, 45. Copies of the submitted comments from industry members, state regulators, including the National Association of Insurance Commissioners, and elected officials, are attached hereto as Group Exhibit 5, sub-parts A-G. Defendants acknowledged that they received public comments regarding the text of the Proposed Order; however, there was never a meaningful, substantive response to any of the public comments from industry representatives or state regulators *Id.* (*See* Ex. 1, 89 Fed. Reg. 23338 at 23340) (acknowledging receipt of public comments). The New Rule indicates that Defendants had considered those public comments, yet there is no indication: 1) that Defendants responded to the public comments[5], or 2) that their actions satisfied the legal concerns raised in the public comments, or 3) how the modified New Rule addresses industry or customer concerns. *Id.* ¶40. Indeed, at one point in the New Rule, Defendants state, "The Departments appreciate these

[5] The New Rule sets forth one instance of a modification related to the word "Warning", which was removed after consumer testing. This was an insignificant modification given the gravity of the remaining portion of the Proposed Order.

comments and suggestions and will take them into consideration in any future regulations or guidance defining STLDI." *Id.* at ¶48 (*See* Ex. 1, 89 Fed. Reg. 23338 at 23367 (April 3, 2024)). Defendant's utter disregard for the administrative rule making process is front and center in the New Rule's rejections. *See generally Ryan LLC v. Fed. Trade Comm'n*, No. 3:24-CV-00986-E, 2024 WL 3297524, at *12 (N.D. Tex. July 3, 2024) (granting injunctive relief, noting FTC's administrative requirements to consider alternative courses of action).

Unfortunately for Defendants, the RFA remains in full force and effect. 5 U.S. § 601, et. seq. The RFA requires that Defendants conduct a regulatory flexibility analysis. 5 U.S.C. § 603. Part of that analysis requires "a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply § 603(b)(3). It also requires that "any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any increase in the cost of credit for small entities." § 603(d)(1)(b). Defendants' New Rule feigns compliance with the RFA by including superficial data. Comp. ¶43. But Defendants' New Rule is replete with admissions that the regulatory flexibility analysis was not done in an attempt to satisfy the requirements of the RFA, in a section entitled, "Costs to Agents and Brokers," the New Rule notes that "The Departments sought information on the number of agents and brokers who sell STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage, respectively, and how their compensation might be affected by the provisions proposed in the 2023 proposed rules." *Id.* at 43-45 (*See* Ex.1, 89 Fed. Reg. 23338 at 23301 (April 3, 2024).

By way of example—and not an exhaustive itemization of each tacit admission of insufficiency of their analysis in the New Rule—the following statements demonstrate the lack of data and inauthentic attempts to perform a proper analysis:

- "However, the Departments lack data about the number of agents and brokers that currently enroll individuals in STLDI or fixed indemnity excepted benefits coverage and did not receive any additional data from commenters." *See* Ex. 1, 89 Fed. Reg. 23338 at 23398 - 23399 (April 3, 2024).
- "However, due to a lack of data, the Departments were unable to precisely estimate how many agents and brokers might be affected by the 2023 proposed rules and the magnitudes of the potential changes in compensation.350 The Departments solicited comments on the number of agents and brokers who sell STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage, respectively, and how their compensation might be affected by the 2023 proposed rules." *See* Ex. 1, 89 Fed. Reg. 23338 at 23407 (April 3, 2024) (footnote omitted).

- The New Rule ultimately concluded that "due to a lack of data and information, there are several areas of uncertainty regarding the potential market impacts of these final rules. As a result, there is also some uncertainty about the potential impact on the compensation of agents and brokers." ." *See* Ex. 1, 89 Fed. Reg. 23338 at 23408 (April 3, 2024).

Comp. ¶45. Defendants' New Rule, on its face, establishes that their analysis is incomplete and flawed. *Id.* ¶46. One need not look past Table 1, entitled "Accounting Table," that unequivocally establishes that the New Rule cannot quantify the following "Costs":

• Potential increase in premium costs for individuals who switch from STLDI or fixed indemnity excepted benefit coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and who are not eligible for the PTC.
• Potential increase in the number of uninsured individuals or the number of individuals experiencing a coverage gap, if some individuals with STLDI coverage purchased after the applicability date are no longer able to renew or extend their current policy, choose not to purchase a new policy from another issuer of STLDI, and can only obtain comprehensive coverage during open enrollment, or choose not to purchase comprehensive coverage.
• Potential decrease in compensation for agents and brokers if there is a reduction in sales of STLDI and fixed indemnity excepted benefits coverage.
• Potential increase in health care spending, if individuals switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and increase their use of health care as a result.
• Potential costs to States, if States enact or implement new legislation in response to these final rules.
• Potential costs to State departments of insurance associated with reviewing amended marketing materials and plan documents filed by issuers of STLDI

> and fixed indemnity excepted benefits coverage in response to these final rules. *Id.*, ¶46 (*See* Ex. 1, 89 Fed. Reg. 23338 at 23394, Table 1: Accounting Table, Non-Quantified (April 3, 2024)).

The New Rule does not provide any objective analysis of: (1) the numbers of consumers of the public who may lose coverage, experience a gap in coverage, or have an increase in premiums to obtain coverage elsewhere; (2) what the cost to agents and brokers will be; or (3) even what the costs will be to the States, which bear the ultimate legislative authority to regulate the business of insurance. *Id.*, ¶47.

Next, Defendants' New Rule does not satisfy the Significant Alternative requirements of the RFA because, if the intent of the New Rule was to distinguish STLDI plans and FII plans from comprehensive health insurance and to "increase consumer awareness of coverage options," There was a whole host of Significant Alternatives provided to Defendants as part of the comments submitted. *Id.* ¶48 (*See* Ex. 1, 89 Fed. Reg. 23338 at 23346 (April 3, 2024)). But in response, Defendants simply noted that "[t]he Departments appreciate these comments and suggestions and will take them into consideration in any future regulations or guidance defining STLDI." *Id.*; *See* Ex. 1, 89 Fed. Reg. 23338 at 23367 (April 3, 2024).

Given the unknown potential impact of this substantial sudden shift from the existing 2018 Rule for STLDI plans, the RFA requires Defendants to look at Significant Alternatives. *Id.* ¶49; 5 U.S.C. § 603(c). Initial regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act of 1980, as amended, is taken from Title 5 of the United States Code, sections 601–612. *Id.* ¶49. Yet despite these edicts, Defendants' New Rule only provides a conclusory, passing statement regarding the Significant Alternatives requirement. The Proposed Order states, in pertinent part:

> "The regulatory alternatives considered in developing these rules are discussed in section V.C of this preamble. The Departments are of the view

> that none of these alternatives would both achieve the policy objectives and goals of these final rules as previously stated and be less burdensome to small entities." Comp., ¶50 (*See* Ex. 1, 89 Fed. Reg. 23338 at 23408 (April 3, 2024)).

Remarkably, the Preamble does not set forth any Significant Alternatives to satisfy RFA requirements. *Id.* ¶51. There is also no substantive analysis whether there is an acceptable Significant Alternative to fulfill the purported purpose behind Defendants' New Rule. *Id.* ¶¶52-53. Rather than taking a less draconian position—as was suggested by commentors—Defendants promulgated a rule that 1) does not accomplish the intended goal of the revision to the rule, and 2) renders a long-recognized insurance product functionally useless. *Id.* ¶¶4, 12, 37, 42, 79 (*See generally* 89 Fed. Reg. 23338 (April 3, 2024)).

Given the lack of a substantive flexibility analysis, the New Rule also does not satisfy § 608 of the RFA, in that there is no emergency to warrant a waiver of RFA requirements. *Id.* ¶52. Indeed, the current rule has been in place since 2018, and there is no evidence of a dire or emergency situation that would alleviate Defendants' obligation to promulgate administrative rules in accordance with the RFA. *Id.* Ultimately, the New Rule equates duration and renewals with consumer awareness, without any explanation of how limiting duration of STLDI plans or requiring different coverage for FII Plans fosters "consumer awareness of coverage options." *Id.* ¶53. Thus, the New Rule is a *de facto* prohibition of these plans, and both the creation process and the substance of the New Rule violates the necessary rulemaking requirements. *Id.*

ii. Defendants exceeded their authority.

The New Rule seeks to re-write legislation so that Defendants can implement their four-month STLDI definition within a given coverage-year relying upon section 2791(b)(5) of the PHS Act. *Id.* ¶54. But the PHS Act does not vest Defendants the authority to legislate vis-à-vis the rule making process. *Id.* ¶55. Rather, this statutory provision provides that "[t]he term 'individual

health insurance coverage' means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited-duration insurance." *Id.* ¶56 (Section 2791(b)(5) (Emphasis added)). The meaning of this express statutory definition—directed by Congress decades prior—is clear: "Short-term, limited-duration insurance" is not individual health insurance coverage. *Id.* Defendants' New Rule seeks to create two legislative definitions from one term. Defendants take the term, "short-term, limited-duration insurance," and subdivide it to create more restrictive definitions. *Id.* ¶57.

There is no authority supporting Defendants' interpretation of the limited term duration. *Id.* ¶58. Defendants' New Rule takes umbrage with "stacking" the STLDI plans, but the limitation on stacking is nowhere to be found in the PHS Act, nor is it prohibited in any other legislation. *Id.* Defendants' New Rule to limit the duration and number of renewals for STLDI plans is more properly a legislative act that is unauthorized by administrative fiat. *Id.* ¶59. Defendants' attempt to create a limitation where none exists in the statute is unlawful, beyond Defendants' rule making authority, arbitrary, and capricious. *Id.*

STATEMENT OF NATURE AND STAGE OF PROCEEDING

AAAB filed its Complaint on August 28, 2024 (ECF #1). AAAB's claims arise under the APA, 5 U.S.C. § 706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. The Department has not yet responded to the amended complaint.

STATEMENT OF ISSUES AND STANDARD OF REVIEW

The issue presented is whether a stay of the effective date of Defendants' New Rule and a preliminary injunction prohibiting Defendants from enforcing the Rule is warranted. AAAB is entitled to a preliminary injunction if "(1) [it is] likely to succeed on the merits, (2) [it is] likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in [its]

favor, and (4) an injunction is in the public interest." *McDonald v. Longley*, 4 F.4th 229, 255 (5th Cir. 2021) (quotation marks omitted).

The likelihood of success is a prima facie showing and not a burden of summary judgment. *Janvey v. Alguire*, 647 F.3d 585, 595–96 (5th Cir. 2011). Nor does it mean "certain." *Ryan LLC*, No. 3:24-CV-00986-E, 2024 WL 3297524, at *6 (quoting *Byrne v. Roemer*, 847 F.2d 1130, 1133 (5th Cir. 1988)). Irreparable harm "must be more than 'speculative,'" and "there must be more than an unfounded fear on the part of the applicant." *Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (affirming district court's finding in granting motion for preliminary injunction).

ARGUMENT:

Defendants' New Rule is a gross abuse of statutory and constitutional limits on government power. It runs roughshod over the preexisting scheme and will massively and needlessly disrupt the business operations of AAAB and countless other U.S. employers, as well as displace coverage for hundreds of thousands of policyholders nationwide. The New Rule should be stayed and the Department be prohibited from enforcing it, unless and until the agency can justify the Rule on the merits before this Court.

I. AAAB has made a prima facie showing of likelihood to succeed on the merits.

AAAB is likely to succeed because Defendants' New Rule is patently unlawful. The text, history, and structure of Defendants' latent rule make clear that Defendants lacked the sweeping power to issue such rules restricting STLDI. Were there any doubt, the major questions doctrine would resolve it. But even if Defendants' approach were correct, it would be an unconstitutional delegation of legislative authority because Defendants lacked an intelligible principle guiding their exercise of such rulemaking authority.

a. Defendants lack textual authority to effect this STLDI substantive rulemaking, and deference is presumptively not appropriate.

The Department claims authority under the PHS Act Section 2701 through 2728, but it does not grant the substantive rulemaking authority the Defendants seek to exercise. After decades of required judicial deference to administrative agencies, the U.S. Supreme Court recently struck that deference in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244. *See Texas v. United States Dep't of Labor*, 4:24-CV-499-SDJ, 2024 WL 3240618, at **6, 15-16 (E.D. Tex. June 28, 2024) ("carefully following *Loper Bright*'s controlling guidance and the APA," granting a preliminary injunction, where Department changed overtime exemption statuses for millions of employees). *Loper Bright Enterprises* ended the forty-year-old "*Chevron* deference," which had directed courts to defer to the expertise of agencies on how to interpret ambiguous statutory language as pertaining to their work. *Id*.

The *Loper Bright* Court looked to the fishery conservation Act for the bounds of administratively regulating fishery resources. *Loper Bright Enterprises*, 144 S. Ct. at 2254. Along with the mandatory provisions, the Act allowed additional discretionary provisions, including the specification that observers be carried on board domestic vessels for the purpose of collecting data necessary for fishery conservation and management. *Id.* at 2254-55. But several years later, the Department of Commerce's National Marine Fisheries Service promulgated a rule approving an amendment to management plans to require fishermen to pay for those observers whenever federal funding became unavailable. *Id.* at 2255. Petitioners challenged that Rule under the Act, which incorporated the APA. They argued that the Act did not authorize NMFS to mandate that Petitioners pay for observers required by a fishery management plan. *Id.* at 2256.

The Court noted in its analysis that under the prior *Chevron* doctrine, courts sometimes deferred to "permissible" agency interpretations of administrative statutes—even when a

reviewing court read the statute differently. *Id.* at 2247. But the Court reasoned that such deference could not be squared with the APA, and *Chevron* deference accordingly failed. *Id.* at 2244, 2247. Consequently, it held that courts must always exercise independent judgment in deciding whether an agency acted within its statutory authority, and held that under the APA, courts cannot defer to an agency's interpretation of the law simply because a statute may be ambiguous. *Id.* at 2244. Rather, under the APA, it "remains the responsibility of [a] court to decide whether the law means what the agency says." *Id.* at 2261 (quoting *Perez v. Mortgage Bankers Assn.*, 575 U.S. 92, 109 (2015).

i. Lack of statutory authority.

Under the APA, statutory interpretation is primarily a judicial function. *See Loper Bright Enterprises*, 144 S. Ct. at 2261-62 ("Courts are tasked with exercising independent judgment to determine the meaning of statutory provisions, even when those provisions are ambiguous."). The APA reinforces this principle, specifying that courts, not agencies, will decide all relevant questions of law arising on review of agency action, and Courts must set aside any action inconsistent with the law as interpreted by the courts. *See Id.* (explaining that "[t]he APA thus codifies for agency cases the unremarkable, yet elemental proposition reflected by judicial practice dating back to *Marbury*."); *see also Ryan LLC*, No. 3:24-CV-00986-E, 2024 WL 3297524, at *7 ("The judiciary remains the final authority with respect to questions of statutory construction and must reject administrative agency actions which exceed the agency's statutory mandate or frustrate congressional intent.") (citing *Am. Fin. Servs. Ass'n v. FTC*, 767 F.2d 957, 968 (D.C. Cir. 1985)).

Under the APA, "the reviewing court shall decide all relevant questions of law, [and] interpret constitutional and statutory provisions," and wherever statutory terms "are not defined by the statute and their exact meaning is in dispute, the courts ultimately determine as a matter of

law what th[ose terms] include." *Obremski v. Office of Pers. Mgmt. & Merit Sys. Prot. Bd.*, 699 F.2d 1263, 1269 (D.C. Cir. 1983) (quoting 5 U.S.C. § 706 (1976) and *FTC v. Gratz*, 253 U.S. 421, 427 (1920)). When a court's inquiry concerns an agency's statutory interpretation, the threshold question is whether Congress has directly spoken to that precise question at issue. *Lipsman v. Sec'y of Army*, 335 F. Supp. 2d 48, 52 (D.D.C. 2004). If Congressional intent is clear, then it is determinative. *Id.* But if the statute is silent or ambiguous, the court must determine whether the agency's action is based on a permissible construction of the statute. *Id.* Thus, questions of law are without deference and a reviewing court must set aside agency policymaking and factfinding that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *Loper Bright Enterprises*, 144 S. Ct. at 2261. Resolution of statutory ambiguities involves policymaking with legal interpretation and remains the domain of the Judiciary. *See Id.* at 2267-68 ("the view that interpretation of ambiguous statutory provisions amounts to policymaking suited for political actors rather than courts is especially mistaken because it rests on a profound misconception of the judicial role. Resolution of statutory ambiguities involves legal interpretation, and that task does not suddenly become policymaking just because a court has an 'agency to fall back on.'").

The ultimate impact of the Final Rule is to require members of the public to secure an ACA Plan or forego health coverage. Congress previously eliminated the penalty for the individual mandate requirement, which ultimately led to the invalidation of the individual mandate. But the timing of the effective date of this New Rule is of no coincidence. If the STLDI plans are only effective for a total duration of four months, then consumers could not renew a STLDI plan on January 1, 2025, and would be forced to secure an ACA or equivalent plan from a private carrier, with no regard to the premium or deductibles to be borne by the consumer.

In essence, Defendants are using the rule making process to override a Congressional act and judicial precedent, which is not allowed and is beyond Defendants' authority. "[T]here is a substantial likelihood" that a "Rule is arbitrary and capricious [when] it is unreasonably overbroad without a reasonable explanation." *Ryan LLC*, No. 3:24-CV-00986-E, 2024 WL 3297524, at *11 (finding FTC's "one-size-fits-all approach . . . fails to establish a 'rational connection between the facts found and the choice made'").

1. Text and history

"Congress … does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). But this is exactly what Defendants contend Congress is to have done. There is no doubt that "[a]dministrative agencies are creatures of statute," which "possess only the authority that Congress has provided." *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab.*, 595 U.S. 109, 117 (2022). *See Ryan LLC*, No. 3:24-CV-00986-E, 2024 WL 3297524, at *9 (Brown, J., cautioning, "Agencies are creatures of Congress—'an agency literally has no power to act . . . unless and until Congress confers power upon it.'") (quoting *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)).

But here, there is no authority in the statutory text. Congress cannot be understood to have also granted substantive rulemaking authority over STLDI terms to the Department. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468, 471 (2001) (no statutory authority for EPA to consider costs of air quality standards when not included in statute).

2. The major questions doctrine confirms the Department's lack of authority in this massive power exercise.

Were there any doubt remaining, it would be resolved by the major questions doctrine. *W. Virginia v. Envtl. Prot. Agency*, 597 U.S. 697, 716 (2022). This doctrine embodies the "common

sense" principle that Congress does not delegate massive powers in "vague terms." *Id.* at 716. Agencies cannot regulate "a question of deep economic and political significance" absent "clear" authority from Congress. *Biden v. Nebraska*, 600 U.S. 477, 505-06 (2023) (reasoning that in *King v. Burwell*, 473, 485 (2015), "we declined to defer to the Internal Revenue Service's interpretation of a healthcare statute, where the provision at issue affected 'billions of dollars of spending each year and . . . the price of health insurance for millions of people."). As in *Burwell*, the Court will not assume that Congress entrusted any task to an administrative agency—an agency whose outlook on policy matters could fluctuate with each election and change in administration—without a clear statement to that effect. *Id.* at 506.

Defendants' New Rule bears similar "'economic and political significance'" to recent applications of the major questions doctrine. *Id.* at 505. The *West Virginia* Court applied the major questions doctrine to an EPA plan to shift power generation away from fossil fuels that would have: "entail[ed] billions of dollars in compliance costs," "require[d] the retirement of dozens of coal-fired power plants, and eliminate[d] tens of thousands of jobs." *West Virginia*, 597 U.S. at 714. In *Biden v. Nebraska*, 143 S. Ct. 2355 (2023), the Court applied the major questions doctrine to a plan "to release 43 million borrowers from their obligations to repay $430 billion in student loans." *Id.* at 2372. The doctrine was similarly applied to a federal eviction moratorium that had been estimated to cause an "economic impact" of approximately $50 billion. *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764 (2021).

Here, it is estimated that the economic impact will cost billions of dollars. Such an "exercise [of] control over 'a significant portion of the American economy'" triggers application of the major questions doctrine. *Nebraska*, 143 S. Ct. at 2372. Defendants' New Rule, changing the landscape of STLDI, indisputably has enormous economic significance. The major questions

doctrine also applies when an agency—such as here—seeks to effectuate "fundamental revision of [a] statute, changing it from one sort of scheme of regulation into an entirely different kind." *W. Virginia*, 597 U.S. at 728 (brackets and ellipsis omitted).

b. Such a delegation would be unconstitutional as effected.

The Constitution vests "[a]ll [the] legislative Powers" that it grants in Congress. U.S. Const. art. I, § 1. Congress "is not permitted to abdicate or to transfer to others the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. U.S.*, 295 U.S. 495, 529 (1935). Consequently, Congress may not "delegate . . . powers which are strictly and exclusively legislative." *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42 (1825).

Rather, Congress can only delegate power to an agency if it first provides an "intelligible principle" by which the agency could exercise that power. *Mistretta v. U.S.*, 488 U.S. 361, 372 (1989). More precisely, Congress may authorize agencies only to "fill[] up details and find[] facts." *See Gundy v. U.S.*, 588 U.S. 128, 179 (2019) (Gorsuch, J., dissenting, "while Congress can enlist considerable assistance from the executive branch in filling up details and finding facts, it may never hand [legislative power] off . . . That 'is delegation running riot.'") (quoting *A.L.A. Schechter Poultry*, 295 U.S. at 553) (Cardozo, J., concurring)).

Congress did not provide an intelligible principle to guide any rulemaking that would define STLDI terms. At minimum, Defendants' interpretation of its authority for exercise of power urges caution post-*Loper Bright*. In the aftermath of *Loper Bright*'s overturn of *Chevron* deference, the U.S. District Court for the Eastern District of Texas—when granting a motion for a preliminary injunction against the D.O.L's 2024 Rule that raised the minimum salary levels for the executive, administrative, and professional (EAP) employee exemption under the Fair Labor Standards Act—admonished that "[a]dministrative agencies are creatures of statute;" therefore, they "must point

to explicit Congressional authority justifying their decisions." *State of Texas v. U.S. Dept. of Labor*, No. 4:24-CV-499-SDJ, 2024 WL 3240618, at *7 (quoting *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 595 U.S. 109, 117). In determining whether a statute granted an agency the authority it claims to have, the court looked at the statute's text, as explaining the statutory interpretation "begins with the statutory text, and ends there as well if the text is unambiguous." *Id*. Even then, "ambiguous statutory language [must] be construed to avoid serious constitutional doubts." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009). Those constitutional doubts are such that this structure does not provide authority for Defendants to promulgate their New Rule.

II. AAAB will suffer imminent, irreparable harm without a stay or preliminary injunction, which also renders proceeding under Local Rule CV-7(e) inadequate.

First, AAAB and its membership (not to mention the public) have incurred the "nonrecoverable costs of complying with a putatively invalid regulation" before the Final Rule goes into effect. *Rest. Law Ctr. v. U.S. Dep't of Labor*, 66 F.4th 593, 597 (5th Cir. 2023). This includes costs associated with new notices, efforts to assist consumers with new options in a compressed timeframe or risk exposing consumers to gaps in coverage, and AAAB will lose STLDI policies that would otherwise be valid. A district court has "general discretionary power to stay proceedings before it in the control of its docket and in the interests of justice," and "[t]he same standards apply 'to prevent irreparable injury' under the APA." *See Ryan LLC*, No. 3:24-CV-00986-E, 2024 WL 3297524, at **5, 14 (concluding irreparable harm, where compliance with the Rule would result in unrecoverable financial injury) (quoting *McKnight v. Blanchard*, 667 F.2d 477, 479 (5th Cir. 1982) and citing 5 U.S.C. § 705).

III. The balance of equities and public interest favor preliminary relief.

The balance of equities and public interest "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, those merged interests support a stay and preliminary injunction. There is "no public interest in the perpetuation of unlawful agency action." *Texas v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021). And "our system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors*, 594 U.S. at 766.

More than that, a nationwide preliminary injunction will "maintain[] … the status quo." *Dayton Bd. of Educ. v. Brinkman*, 439 U.S. 1358, 1359 (1978). Namely, that status quo is the current 2018 Rule. Millions of insured persons and countless businesses, including AAAB, "have serious reliance interests on preserving the status quo," which allows them to ensure temporary insurance coverage. *See Texas v. Becerra*, 577 F. Supp. 3d 527, 561 (N.D. Tex. 2021) (granting preliminary injunction where interim final rule imposing COVID mask and vaccine mandate "constitute[d] a drastic change from . . . 'precedent.'"); *see also Ryan LLC*, No. 3:24-CV-00986-E, 2024 WL 3297524, at *5, n. 4, **14-16 (finding great public interest to maintain the status quo and no harm on the agency, acknowledging Fifth Circuit's affirmances of nationwide injunctive relief, and granting order staying the September 4, 2024 effective date of the FTC's Non-Compete Rule and preliminarily enjoining the FTC from enforcing the Rule—including, but not limited to, ongoing or future administrative action.).

In contrast to the public interests, a preliminary injunction for the government "will do [the Department] no harm whatsoever." *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021). A few months' wait to enforce a change of this magnitude is a small apprehension for a big step. In short, the risk of error is ultimately greater to Plaintiff, the insurance industry and the public, if a preliminary injunction is denied than if it is granted. The question in the case is whether

the Court—at the behest of unelected, unaccountable bureaucrats—should uphold the eradication of insurance policies for millions of Americans or should vacate one unprecedented and illegal Rule. Until this matter is fully litigated, the appropriate course is plain.

CONCLUSION

For the foregoing reasons, AAAB respectfully requests that this Court stay the effective date of this Rule and enter a preliminary injunction of its enforcement.

Respectfully submitted:

By: ***/s/ Dominick L. Lanzito***

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EXHIBIT 1

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9990]

RIN 1545–BQ28

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AC12

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, and 148

[CMS–9904–F]

RIN 0938–AU67

Short-Term, Limited-Duration Insurance and Independent, Noncoordinated Excepted Benefits Coverage

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document sets forth final rules that amend the definition of short-term, limited-duration insurance, which is excluded from the definition of individual health insurance coverage under the Public Health Service Act. This document also sets forth final rules that amend the regulations regarding the requirements for hospital indemnity or other fixed indemnity insurance to be considered an excepted benefit in the group and individual health insurance markets.

DATES: These regulations are effective on June 17, 2024.

FOR FURTHER INFORMATION CONTACT: Shannon Hysjulien or Rebecca Miller, Employee Benefits Security Administration, Department of Labor at (202) 693–8335; Jason Sandoval, Internal Revenue Service, Department of the Treasury at (202) 317–5500; Cam Clemmons, Centers for Medicare & Medicaid Services, Department of Health and Human Services at (206) 615–2338; Lisa Cuozzo, Centers for Medicare & Medicaid Services, Department of Health and Human Services at (667) 290–8537.

SUPPLEMENTARY INFORMATION:

I. Background

These final rules set forth revisions to the definition of "short-term, limited-duration insurance" (STLDI) for purposes of its exclusion from the definition of "individual health insurance coverage" in 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 144. The definition of STLDI is also relevant for purposes of the disclosure and reporting requirements in section 2746 of the Public Health Service Act (the PHS Act), which require health insurance issuers offering individual health insurance coverage or STLDI to disclose to enrollees with individual health insurance or STLDI coverage, and to report annually to the Department of Health and Human Services (HHS), any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage.

These final rules also set forth amendments to the regulations regarding the requirements for hospital indemnity and other fixed indemnity insurance to be treated as an excepted benefit in the group and individual health insurance markets (fixed indemnity excepted benefits coverage).[1] As explained in greater detail later in this section of the preamble, the Department of the Treasury (Treasury Department), the Department of Labor, and HHS (collectively, the Departments) are not finalizing certain aspects of the proposed rules regarding fixed indemnity excepted benefits coverage and the Treasury Department and the Internal Revenue Service (IRS) are not finalizing the proposed amendments to Treasury Reg. § 1.105–2 at this time.

In proposed rules published on July 12, 2023, in the **Federal Register** titled "Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance" (2023 proposed rules),[2] the Departments proposed revisions to define and more clearly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage. Comprehensive coverage is coverage that is subject to the Federal consumer protections and requirements established under chapter 100 of the Internal Revenue Code (Code), part 7 of the Employee Retirement Income Security Act of 1974 (ERISA), and title XXVII of the PHS Act (hereinafter referred to as the Federal consumer protections and requirements for comprehensive coverage),[3] such as the prohibition on exclusions for preexisting conditions, the prohibition on health status discrimination, and the requirement to cover certain preventive services without cost sharing. The Departments proposed these revisions to promote equitable access to high-quality, affordable, comprehensive coverage by increasing consumers' understanding of their health coverage options and reducing misinformation about STLDI and fixed indemnity excepted benefits coverage, consistent with Executive Orders 14009 and 14070 as described in section I.B of this preamble. The Treasury Department and the IRS also proposed amendments to Treasury Reg. § 1.105–2 to clarify the tax treatment of benefit payments in fixed amounts under hospital indemnity or other fixed indemnity coverage purchased on a pre-tax basis.

The Departments also solicited comments regarding coverage only for a specified disease or illness that qualifies as excepted benefits (specified disease excepted benefits coverage),[4] and regarding level-funded plan arrangements[5] to better understand the key features and characteristics of these arrangements and whether additional guidance or rulemaking is needed to clarify plan sponsors' and issuers' obligations with respect to coverage provided through these arrangements. While specified disease excepted benefits coverage and level-funded plan arrangements are not addressed in these final rules, the Departments appreciate the comments received on these topics and will take them into consideration as they determine whether additional guidance or rulemaking is warranted in the future.

A. General Statutory Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, August 21, 1996) added chapter 100 to the Code, part 7

[1] For simplicity and readability, this preamble refers to hospital indemnity or other fixed indemnity insurance that meets all requirements to be considered an excepted benefit under the Federal framework as "fixed indemnity excepted benefits coverage" to distinguish it from hospital indemnity or other fixed indemnity insurance that does not meet all such requirements.

[2] 88 FR 44596 (July 12, 2023).

[3] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

[4] 88 FR 44596 at 44632 (July 12, 2023).

[5] *Id.* at 44632–34.

to ERISA, and title XXVII to the PHS Act, which set forth portability and nondiscrimination rules with respect to health coverage. These provisions of the Code, ERISA, and the PHS Act were later augmented by other laws, including the Mental Health Parity Act of 1996 (Pub. L. 104–204, September 26, 1996), the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. 110–343, October 3, 2008), the Newborns' and Mothers' Health Protection Act (Pub. L. 104–204, September 26, 1996), the Women's Health and Cancer Rights Act (Pub. L. 105–277, October 21, 1998), the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110–233, May 21, 2008), the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111–3, February 4, 2009), Michelle's Law (Pub. L. 110–381, October 9, 2008), the Patient Protection and Affordable Care Act (Pub. L. 111–148, March 23, 2010) (as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, March 30, 2010) (collectively known as the Affordable Care Act (ACA)), and Division BB of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), which includes the No Surprises Act.

The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 9815 of the Code and section 715 of ERISA to incorporate the provisions of part A of title XXVII of the PHS Act, as amended or added by the ACA, into the Code and ERISA, making them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The provisions of the PHS Act incorporated into the Code and ERISA, as amended or added by the ACA, are sections 2701 through 2728.

In addition to market-wide provisions applicable to group health plans and health insurance issuers in the group and individual markets, the ACA established Health Benefit Exchanges (Exchanges) aimed at promoting access to high-quality, affordable, comprehensive coverage. Section 1401(a) of the ACA added section 36B to the Code, providing a premium tax credit (PTC) for certain individuals with annual household income that is at least 100 percent but not more than 400 percent of the Federal poverty level (FPL) who enroll in, or who have a member of their tax household enrolled in, an individual market qualified health plan (QHP) through an Exchange who are not otherwise eligible for minimum essential coverage (MEC). Section 1402 of the ACA provides for, among other things, reductions in cost sharing for essential health benefits for qualified low- and moderate-income enrollees in silver-level QHPs purchased through the individual market Exchanges. Section 1402 also provides for reductions in cost sharing for American Indians enrolled in QHPs purchased through the individual market Exchanges at any metal level.

Section 5000A of the Code, added by section 1501(b) of the ACA, provides that individuals must maintain MEC, or make a payment known as the individual shared responsibility payment with their Federal tax return for the year in which they did not maintain MEC, if they are not otherwise exempt.[6] On December 22, 2017, the Tax Cuts and Jobs Act (Pub. L. 115–97) was enacted, which included a provision under which the individual shared responsibility payment under section 5000A of the Code was reduced to $0, effective for months beginning after December 31, 2018.

The American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) was enacted on March 11, 2021. Among other policies intended to address the health care and economic needs of the country during the coronavirus disease 2019 (COVID–19) pandemic, the ARP increased the PTC amount for individuals with annual household income at or below 400 percent of the FPL and extended PTC eligibility for the first time to individuals with annual household incomes above 400 percent of the FPL. Although the expanded PTC subsidies under the ARP were applicable only for 2021 and 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022) extended the subsidies for an additional 3 years, through December 31, 2025.

The No Surprises Act was enacted on December 27, 2020, as title I of Division BB of the CAA, 2021. The No Surprises Act added new provisions in Subchapter B of chapter 100 of the Code, part 7 of ERISA, and part D of title XXVII of the PHS Act, applicable to group health plans and health insurance issuers offering group or individual health insurance coverage. These provisions provide protections against surprise medical bills for certain out-of-network services and generally require plans, issuers, providers, and facilities to make certain disclosures regarding balance billing protections to the public and to individual participants, beneficiaries, and enrollees. In addition to the new provisions applicable to group health plans and issuers of group or individual health insurance coverage, the No Surprises Act added a new part E to title XXVII of the PHS Act, establishing corresponding requirements applicable to health care providers, facilities, and providers of air ambulance services. The CAA, 2021 also amended title XXVII of the PHS Act to, among other things, add section 2746, which requires health insurance issuers offering individual health insurance coverage or STLDI to disclose the direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in individual health insurance coverage or STLDI to the enrollees in such coverage as well as to report such compensation annually to HHS.

The Secretaries of the Treasury, Labor, and HHS have authority to issue such regulations as may be necessary or appropriate to carry out the parallel provisions under the Code, ERISA, and the PHS Act, including the definitions in section 9832 of the Code, section 733 of ERISA, and section 2791 of the PHS Act.[7] [8]

B. Recent Executive Orders

On January 28, 2021, President Biden issued Executive Order 14009, "Strengthening Medicaid and the Affordable Care Act," which directed the Departments to review policies to ensure their consistency with the Administration's goal of protecting and strengthening the ACA and making high-quality health care accessible and affordable for every American.[9] Executive Order 14009 also directed Federal agencies to examine policies or practices that may undermine protections for people with preexisting conditions and that may reduce the affordability of coverage or financial

[6] Section 5000A of the Code and Treasury regulations at 26 CFR 1.5000A–3 provide exemptions from the requirement to maintain MEC for the following individuals: (1) members of recognized religious sects; (2) members of health care sharing ministries; (3) exempt noncitizens; (4) incarcerated individuals; (5) individuals with no affordable coverage; (6) individuals with household income below the income tax filing threshold; (7) members of Federally recognized Indian tribes; (8) individuals who qualify for a hardship exemption certification; and (9) individuals with a short coverage gap of a continuous period of less than 3 months in which the individual is not covered under MEC. The eligibility standards for exemptions can be found at 45 CFR 155.605.

[7] Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

[8] *See also* 64 FR 70164 (December 15, 1999).

[9] Executive Order 14009 of January 28, 2021, 86 FR 7793 (February 2, 2021).

assistance for coverage. Executive Order 14009 also revoked the previous Administration's Executive Order 13813, "Promoting Healthcare Choice and Competition Across the United States," which directed agencies to expand the availability of STLDI.[10] On April 5, 2022, President Biden issued Executive Order 14070, "Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage," which directed the heads of Federal agencies with responsibilities related to Americans' access to health coverage to examine polices or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage; that strengthen benefits and improve access to health care providers; that improve the comprehensiveness of coverage and protect consumers from low-quality coverage; and that help reduce the burden of medical debt on households.[11]

In addition, on January 21, 2021, President Biden issued Executive Order 13995, "Ensuring an Equitable Pandemic Response and Recovery," which directed the Secretaries of Labor and HHS, and the heads of all other agencies with authorities or responsibilities relating to the COVID–19 pandemic response and recovery, to consider any barriers that have restricted access to preventive measures, treatment, and other health services for populations at high risk for COVID–19 infection, and modify policies to advance equity.[12]

Consistent with these executive orders, the Departments reviewed the regulatory provisions related to STLDI and fixed indemnity excepted benefits coverage and, after carefully considering public comments received, are finalizing amendments to those provisions in these final rules.

C. Short-Term, Limited-Duration Insurance (STLDI)

STLDI is a type of health insurance coverage sold by health insurance issuers that typically fills temporary gaps in coverage that may occur when an individual is transitioning from one plan or coverage to another, such as transitioning between health coverage offered by one employer to health coverage offered by another employer. Section 2791(b)(5) of the PHS Act provides that "[t]he term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited duration insurance." [13] The PHS Act does not, however, define the phrase "short-term, limited duration insurance." Sections 733(b)(4) of ERISA and 2791(b)(4) of the PHS Act provide that group health insurance coverage means, "in connection with a group health plan, health insurance coverage offered in connection with such plan." Sections 733(a)(1) of ERISA and 2791(a)(1) of the PHS Act provide that a group health plan is generally any plan, fund, or program established or maintained by an employer (or employee organization or both) for the purpose of providing medical care to employees or their dependents (as defined under the terms of the plan) directly, or through insurance, reimbursement, or otherwise. There is no corresponding provision excluding STLDI from the definition of group health insurance coverage. Thus, any health insurance that is sold in the group market and purports to be STLDI must nonetheless comply with applicable Federal group market consumer protections and requirements for comprehensive coverage, unless the coverage satisfies the requirements of one or more types of group market excepted benefits.

Because STLDI is not individual health insurance coverage, it is generally exempt from the Federal individual market consumer protections and requirements for comprehensive coverage. STLDI is not subject to PHS Act provisions that apply to individual health insurance coverage under the ACA including, for example, the prohibition of preexisting condition exclusions or other discrimination based on health status (section 2704 of the PHS Act), the prohibition on discrimination against individual participants and beneficiaries based on health status (section 2705 of the PHS Act), nondiscrimination in health care (section 2706 of the PHS Act), and the prohibition on lifetime and annual dollar limits on essential health benefits (section 2711 of the PHS Act). In addition, STLDI is not subject to the Federal consumer protections and requirements added to the PHS Act by other laws that apply to individual health insurance coverage, including MHPAEA (Pub. L. 110–343, October 3, 2008) (section 2726 of the PHS Act), and the No Surprises Act, as added by the CAA, 2021. Thus, individuals who enroll in STLDI are not guaranteed these key consumer protections under Federal law.[14] The lack of these key Federal consumer protections is especially problematic when the differences between STLDI and comprehensive individual health insurance coverage are not readily apparent to consumers.

In 1997, the Departments issued interim final rules implementing the portability and renewability requirements of HIPAA (1997 HIPAA interim final rules).[15] Those interim final rules included definitions of individual health insurance coverage, as well as STLDI. That definition of STLDI, which was finalized in rules issued in 2004 and applied through 2016, defined "short-term, limited-duration insurance" as "health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer's consent) that is less than 12 months after the original effective date of the contract." [16]

To address the issue of STLDI being sold as a type of primary coverage, as well as concerns regarding possible adverse selection impacts on the individual market risk pools that were created under the ACA,[17] the Departments published proposed rules on June 10, 2016, in the **Federal Register** titled "Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance" (2016 proposed rules). Those rules proposed to revise the Federal definition of STLDI by shortening the permitted duration of such coverage, and adopting a consumer notice provision.[18] On October 31, 2016, the Departments published final rules in the **Federal Register** titled "Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance" (2016 final rules).[19] The 2016 final rules amended the definition

[10] Executive Order 13813 of October 12, 2017, 82 FR 48385 (October 17, 2017).

[11] Executive Order 14070 of April 5, 2022, 87 FR 20689 (April 5, 2022).

[12] Executive Order 13995 of January 21, 2021, 86 FR 7193 (January 26, 2021).

[13] The definition of individual health insurance coverage (and its exclusion of STLDI) has some limited relevance with respect to certain provisions that apply to group health plans and group health insurance issuers. For example, an individual who loses coverage due to moving out of a health maintenance organization (HMO) service area in the individual market is eligible for a special enrollment period to enroll in a group health plan. *See* 26 CFR 54.9801–6(a)(3)(i)(B), 29 CFR 2590.701–6(a)(3)(i)(B), and 45 CFR 146.117(a)(3)(i)(B).

[14] Some State laws apply some consumer protections and requirements that parallel those in the ACA to STLDI.

[15] 62 FR 16894 (April 8, 1997).

[16] 62 FR 16894 at 16928, 16942, 16958 (April 8, 1997); *see also* 69 FR 78720 (December 30, 2004).

[17] *See* Public Law 111–148, March 23, 2010, section 1312(c)(1) and 45 CFR 156.80.

[18] 81 FR 38019 (June 10, 2016).

[19] 81 FR 75316 (October 31, 2016).

of STLDI to specify that the maximum coverage period must be less than 3 months, taking into account any extensions that may be elected by the policyholder with or without the issuer's consent.[20] In addition, the 2016 final rules stated that the following notice must be prominently displayed in the contract and in any application materials provided in connection with enrollment in STLDI, in at least 14 point type:

THIS IS NOT QUALIFYING HEALTH COVERAGE ("MINIMUM ESSENTIAL COVERAGE") THAT SATISFIES THE HEALTH COVERAGE REQUIREMENT OF THE AFFORDABLE CARE ACT. IF YOU DON'T HAVE MINIMUM ESSENTIAL COVERAGE, YOU MAY OWE AN ADDITIONAL PAYMENT WITH YOUR TAXES.[21]

On June 12, 2017, HHS published a request for information (RFI) in the **Federal Register** titled "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients," [22] which solicited comments about potential changes to existing regulations and guidance that could promote consumer choice, enhance affordability of coverage for individual consumers, and affirm the traditional regulatory authority of the States in regulating the business of health insurance, among other goals.[23] In response to this RFI, HHS received comments that recommended maintaining the definition of STLDI adopted in the 2016 final rules, and comments that recommended expanding the definition to allow for a longer period of coverage. Commenters in support of maintaining the definition adopted in the 2016 final rules expressed concern that expanding the definition could leave enrollees in STLDI at risk for significant out-of-pocket costs and cautioned that expanding the definition of STLDI could facilitate its sale to individuals as their primary form of health coverage, even though such insurance lacks key Federal consumer protections that apply to individual health insurance coverage. Commenters in favor of maintaining the definition in the 2016 final rules also suggested that amending the 2016 final rules to include coverage lasting 3 months or more could have the effect of pulling healthier people out of the individual market risk pools, thereby increasing overall premium costs for enrollees in individual health insurance coverage and destabilizing the individual market.

In contrast, several other commenters stated that changes to the 2016 final rules may provide an opportunity to achieve the goals outlined in the RFI (for example, to promote consumer choice, enhance affordability, and affirm the traditional authority of the States in regulating the business of insurance). These commenters stated that shortening the permitted length of STLDI policies in the 2016 final rules had deprived individuals of affordable coverage options. One commenter explained that due to the increased costs of comprehensive coverage, many financially stressed individuals could be faced with a choice between purchasing STLDI or going without any coverage at all. One commenter highlighted the need for STLDI for individuals who are between jobs for a relatively long period and for whom enrolling in Consolidated Omnibus Budget Reconciliation Act (COBRA) [24] continuation coverage is financially infeasible. Another commenter noted that States have the primary responsibility to regulate STLDI and encouraged the Departments to defer to the States' authority with respect to such coverage.

On February 21, 2018, the Departments published proposed rules in the **Federal Register** titled "Short-Term, Limited-Duration Insurance" (2018 proposed rules) in which the Departments proposed changing the definition of STLDI to have a maximum coverage period of less than 12 months after the original effective date of the contract, taking into account any extensions that may be elected by the policyholder without the issuer's consent.[25] Among other things, the Departments solicited comments on whether the maximum length of STLDI should be less than 12 months or some other duration and under what conditions issuers should be able to allow such coverage to continue for 12 months or longer.[26] In addition, the Departments proposed to revise the content of the consumer notice that must appear in the contract and any application materials provided in connection with enrollment in STLDI. The 2018 proposed rules included two variations of the consumer notice—one for policies that had a coverage start date before January 1, 2019, and the other for policies that had a coverage start date on or after January 1, 2019, the latter of which excluded language referencing the individual shared responsibility payment (which was reduced to $0 for months beginning after December 2018).[27] [28]

Some commenters on the 2018 proposed rules acknowledged that STLDI fills an important role by providing temporary coverage but stated that STLDI should not take the place of comprehensive coverage. These commenters expressed concern that allowing STLDI to be marketed as a viable alternative to comprehensive coverage would subject uninformed consumers to potentially severe financial risks. Commenters who opposed the proposed changes to the definition also expressed concern that such plans would siphon off healthier individuals from the market for individual health insurance coverage, thereby raising premiums for individual health insurance coverage.

Many of these commenters also expressed concerns about the lack of protections for consumers who purchase STLDI, stating that such policies are not a viable option for people with serious or chronic medical conditions due to potential coverage exclusions and benefit limitations in STLDI policies. These commenters further observed that STLDI policies can discriminate against individuals with serious illnesses or preexisting conditions, including individuals with mental health and substance use disorders, older consumers, women, transgender patients, persons with gender identity-related health concerns, and victims of rape and domestic violence. Many of these commenters also expressed concern about aggressive and deceptive marketing practices utilized by marketers of STLDI.

Other commenters highlighted the important role that STLDI could play in providing temporary coverage to individuals who would otherwise be uninsured. These commenters, who supported the proposed changes to the definition, also noted that such changes would allow purchasers of STLDI to obtain the coverage they want at a more affordable price for a longer period.

With respect to the maximum length of the initial contract term for STLDI, most commenters opposed extending the maximum duration beyond 3

[20] *Id.* at 75317–75318.

[21] *Id.*

[22] 82 FR 26885 (June 12, 2017).

[23] *See also* Executive Order 13813 of October 12, 2017, 82 FR 48385 (October 17, 2017) (directing the Secretaries of the Treasury, Labor and HHS ". . . to consider proposing regulations or revising guidance, consistent with law, to expand the availability of [STLDI]. To the extent permitted by law and supported by sound policy, the Secretaries should consider allowing such insurance to cover longer periods and be renewed by the consumer.").

[24] Public Law 99–272, April 7, 1986. COBRA added parallel provisions at Code section 4980B, ERISA sections 601–608, and PHS Act sections 2201–2208.

[25] 83 FR 7437 (February 21, 2018).

[26] *Id.* at 7441.

[27] *Id.* at 7440–7441.

[28] Public Law 115–97, December 22, 2017.

months. Others suggested periods such as less than 6 or 8 months. However, most commenters who supported extending the maximum initial contract term beyond 3 months suggested it should be 364 days. A few commenters suggested more than 1 year. Other commenters stated the maximum length of coverage should be left to the States. Commenters who supported the 2018 proposed rules generally favored permitting renewals of STLDI policies, while those who opposed the 2018 proposed rules generally opposed permitting such renewals.

After reviewing comments and feedback received from interested parties, on August 3, 2018, the Departments published final rules in the **Federal Register** titled "Short-Term, Limited-Duration Insurance" (2018 final rules)[29] with some modifications from the 2018 proposed rules. Specifically, in the 2018 final rules, the Departments amended the definition of STLDI to provide that STLDI is coverage with an initial term specified in the contract that is less than 12 months after the original effective date of the contract, and taking into account renewals or extensions, has a duration of no longer than 36 months in total.[30] The 2018 final rules also finalized the provision that issuers of STLDI must display one of two versions of a notice prominently in the contract and in any application materials provided in connection with enrollment in such coverage, in at least 14-point type. Under the 2018 final rules, the notice must read as follows (with the final two sentences omitted for policies sold on or after January 1, 2019):[31]

> This coverage is not required to comply with certain Federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

[29] 83 FR 38212 (August 3, 2018).

[30] *Id.*

[31] *See id.* at 38222–38225.

D. Independent, Noncoordinated Excepted Benefits: Hospital Indemnity or Other Fixed Indemnity Insurance

Section 9831 of the Code, section 732 of ERISA, and sections 2722(b)–(c) and 2763 of the PHS Act provide that the respective Federal consumer protections and requirements for comprehensive coverage do not apply to any individual coverage or any group health plan (or group health insurance coverage offered in connection with a group health plan) in relation to its provision of certain types of benefits, known as "excepted benefits." These excepted benefits are described in section 9832(c) of the Code, section 733(c) of ERISA, and section 2791(c) of the PHS Act.

HIPAA defined certain types of coverage as "excepted benefits" that were exempt from its portability requirements.[32] The same definitions are applied to describe benefits that are not required to comply with the ACA requirements.[33] There are four statutory categories of excepted benefits: independent, noncoordinated excepted benefits, which are the subject of these final rules; benefits that are excepted in all circumstances;[34] limited excepted benefits;[35] and supplemental excepted benefits.[36]

[32] *See* sections 9831(b)–(c) and 9832(c) of the Code, sections 732(b)–(c) and 733(c) of ERISA, and sections 2722(b)–(c), 2763 and 2791(c) of the PHS Act.

[33] Section 1551 of the ACA. *See also* section 1563(a) and (c)(12) of the ACA. Excepted benefits are also not subject to the consumer protections and requirements added by other Federal laws that apply to comprehensive coverage, including MHPAEA, the Newborns' and Mothers' Health Protection Act, the Women's Health and Cancer Rights Act, the Children's Health Insurance Program Reauthorization Act of 2009, Michelle's Law, and Division BB of the CAA, 2021.

[34] Under section 9832(c)(1) of the Code, section 733(c)(1) of ERISA, and section 2791(c)(1) of the PHS Act, this category includes, for example, accident and disability income insurance, automobile medical payment insurance, liability insurance and workers compensation, as well as "[o]ther similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.".

[35] Under section 9832(c)(2) of the Code, section 733(c)(2) of ERISA, and section 2791(c)(2) of the PHS Act, this category includes limited scope vision or dental benefits, benefits for long-term care, nursing home care, home health care, or community-based care, or other, similar limited benefits specified by the Departments through regulation.

[36] Under section 9832(c)(4) of the Code, section 733(c)(4) of ERISA, and section 2791(c)(4) of the PHS Act, this category includes Medicare supplemental health insurance (also known as Medigap), TRICARE supplemental programs, or "similar supplemental coverage provided to coverage under a group health plan." To be considered "similar supplemental coverage" and thus an excepted benefit, the coverage, whether offered in the group or individual market, must supplement coverage provided under a group health plan. This category does not include coverage that supplements individual health insurance coverage. 26 CFR 54.9831–1(c)(5), 29 CFR 2590.732(c)(5), 45 CFR 146.145(b)(5) and 148.220(b)(7).

The category "independent, noncoordinated excepted benefits" includes coverage for only a specified disease or illness (such as cancer-only policies) and hospital indemnity or other fixed indemnity insurance. These benefits are excepted under section 9831(c)(2) of the Code, section 732(c)(2) of ERISA, and section 2722(c)(2) of the PHS Act only if all of the following conditions are met: (1) the benefits are provided under a separate policy, certificate, or contract of insurance; (2) there is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor; and (3) the benefits are paid with respect to an event without regard to whether benefits are provided with respect to such event under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer.[37] In addition, under existing regulations, hospital indemnity and other fixed indemnity insurance in the group market must pay a fixed dollar amount per day (or other period) of hospitalization or illness, regardless of the amount of expenses incurred, to be considered an excepted benefit.[38] By contrast, in the individual market, under existing regulations, hospital indemnity and other fixed indemnity insurance must also pay benefits in a fixed dollar amount, regardless of the amount of expenses incurred, to be considered an excepted benefit, but is permitted to pay on either a per period of hospitalization or illness, or a per-service basis (for example, $100/day or $50/visit).[39] [40]

The amendments to the regulations regarding independent, noncoordinated excepted benefits coverage that were

[37] *See also* section 2763(b) of the PHS Act (providing that "[the] requirements of this part [related to the HIPAA individual market reforms] shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in paragraph (2), (3), or (4) of section 2791(c) if the benefits are provided under a separate policy, certificate or contract of insurance.").

[38] 26 CFR 54.9831–1(c)(4), 29 CFR 2590.732(c)(4), and 45 CFR 146.145(b)(4).

[39] 45 CFR 148.220(b)(4)(iii).

[40] As discussed further in section I.D.2 of this preamble, the existing individual market regulation also provides that hospital indemnity and other fixed indemnity insurance cannot coordinate between the provision of benefits and an exclusion of benefits under any health coverage to be considered an excepted benefit. See 45 CFR 148.220(b)(4)(ii).

proposed in the 2023 proposed rules and those finalized in these final rules address the conditions that must be met for hospital indemnity and other fixed indemnity insurance in the group or individual markets to be considered excepted benefits under the Federal regulations.

Like other forms of excepted benefits, fixed indemnity excepted benefits coverage does not provide comprehensive coverage. Rather, its primary purpose is to provide income replacement benefits.[41] Benefits under this type of coverage are paid in a flat ("fixed") cash amount following the occurrence of a health-related event, such as a period of hospitalization or illness, subject to the terms of the contract. In addition, benefits are provided at a pre-determined level regardless of any health care costs incurred by a covered individual with respect to the health-related event. Although a benefit payment may equal all or a portion of the cost of care related to an event, it is not necessarily designed to do so, and the benefit payment is made without regard to the amount of health care costs incurred.[42]

Traditionally, benefits under fixed indemnity excepted benefits coverage are paid directly to a policyholder, rather than to a health care provider or facility. The policyholder has discretion over how to use such benefits—including using the payment to cover non-medical expenses, such as childcare or transportation—that may or may not be related to the event that precipitated the payment.[43]

[41] The original version of HIPAA that the House Ways & Means Committee referred to the House floor referred to hospital indemnity or other fixed indemnity insurance as a "hospital or fixed indemnity *income-protection policy*" (emphasis added). *See* H.R. Rep. No. 104–496 part I, at 32 (1996), available at: *https://www.govinfo.gov/content/pkg/CRPT-104hrpt496/pdf/CRPT-104hrpt496-pt1.pdf*. *See also* 79 FR 15818 (March 21, 2014) ("The primary reason fixed indemnity insurance is considered to be an excepted benefit . . . is that its primary purpose is not to provide major medical coverage but to provide a cash-replacement benefit for those individuals with other health coverage.").

[42] Jost, Timothy (2017). "ACA Round-Up: Market Stabilization, Fixed Indemnity Plans, Cost Sharing Reductions, and Penalty Updates," *Health Affairs*, available at: *https://www.healthaffairs.org/do/10.1377/forefront.20170208.058674/full*. ("Fixed indemnity coverage is excepted benefit coverage that pays a fixed amount per-service or per-time period of service without regard to the cost of the service or the type of items or services provided.").

[43] America's Health Insurance Plans (2019). "Supplemental Health Insurance: Hospital or Other Fixed Indemnity, Accident-Only, Critical Illness," available at: *https://www.ahip.org/documents/Supplemental-Health-Insurance-Fast-Facts.pdf*.

1. Group Market Regulations and Guidance

The Departments' 1997 interim final rules implementing the portability and renewability requirements of HIPAA codified at 26 CFR 54.9831–1(c)(4), 29 CFR 2590.732(c)(4), and 45 CFR 146.145(b)(4) established requirements for hospital indemnity and other fixed indemnity insurance to qualify as an excepted benefit in the group market. These requirements, which were effective until February 27, 2005, provided that coverage for hospital indemnity or other fixed indemnity insurance is excepted only if it meets each of the following conditions: (1) the benefits are provided under a separate policy, certificate or contract of insurance; (2) there is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and (3) the benefits are paid with respect to an event without regard to whether benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor.[44]

The Departments' group market regulations for fixed indemnity excepted benefits coverage were first amended in the 2004 HIPAA group market final rules. Those amendments added language to further clarify that to be hospital indemnity or other fixed indemnity insurance that is an excepted benefit, the insurance must pay a fixed dollar amount per day (or per other time period) of hospitalization or illness (for example, $100/day) regardless of the amount of expenses incurred.[45] An example was also added as part of these amendments illustrating that a policy providing benefits only for hospital stays at a fixed percentage of hospital expenses up to a maximum amount per day does not qualify as an excepted benefit.[46] As explained in the 2004 HIPAA group market final rules, the result is the same even if, in practice, the policy pays the maximum for every day of hospitalization.[47]

The Departments later released Frequently Asked Questions (FAQ) on January 24, 2013, to offer additional guidance on the types of hospital indemnity or other fixed indemnity insurance that meet the criteria for fixed indemnity excepted benefits coverage.[48] The Departments issued the FAQ in response to reports that policies were being advertised as fixed indemnity coverage, but were paying a fixed amount on a per-service basis (for example, per doctor visit or surgical procedure) rather than a fixed amount per period (for example, per day or per week). The FAQ affirmed that, under the 2004 HIPAA group market final rules, to qualify as fixed indemnity excepted benefits coverage, the policy must pay benefits on a per-period basis as opposed to on a per-service basis.[49] The FAQ also affirmed that group health insurance coverage that provides benefits in varying amounts based on the type of procedure or item, such as the type of surgery actually performed or prescription drug provided, does not qualify as fixed indemnity excepted benefits coverage because it does not meet the condition that benefits be provided on a per-period basis, regardless of the amount of expenses incurred.[50]

The Departments proposed amendments to the group market regulations for fixed indemnity excepted benefits coverage in the 2016 proposed rules.[51] As explained in those proposed rules, the Departments were concerned that some individuals may mistake these policies for comprehensive coverage that would be considered MEC.[52] To address this confusion, the Departments proposed to adopt a notice provision to inform enrollees and potential enrollees that the coverage is a supplement to, rather than a substitute for, comprehensive coverage, and also proposed to add two illustrative examples to further clarify the condition that benefits must be provided on a per-period basis.[53] The Departments also requested comments on whether to more substantively align the rules for hospital indemnity or other fixed indemnity insurance in the group and individual markets.[54] After consideration of comments, the Departments did not finalize the proposed changes to the group market

[44] 62 FR 16894 at 16903, 16939 through 16940, 16954, and 16971 (April 8, 1997).

[45] 69 FR 78720 at 78735, 78762, 78780, and 78798–78799 (December 30, 2004).

[46] *Id. See also* 26 CFR 54.9831–1(c)(4)(iii), 29 CFR 2590.732(c)(4)(iii), and 45 CFR 146.145(b)(4)(iii).

[47] *Id.*

[48] Frequently Asked Questions about Affordable Care Act Implementation (Part XI) (Jan. 24, 2013), Q7, available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xi.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs11*.

[49] *Id.*

[50] *Id.*

[51] 81 FR 38019 at 38031–38032, 38038, 38042–38043, and 38045–38046 (June 10, 2016).

[52] *Id.* at 38031–38032.

[53] *Id.* at 38031–38032, 38038, 38042–38043, and 38045–38046.

[54] As described in section I.D.2 of this preamble, HHS amended the individual market fixed indemnity excepted benefits coverage regulation to provide additional flexibility, subject to several additional requirements that do not apply in the group market. 79 FR 30239 (May 27, 2014).

regulation but noted their intention to address hospital indemnity and other fixed indemnity insurance in future rulemaking.[55]

2. Individual Market Regulations and Guidance

HHS also issued an interim final rule in 1997 establishing the regulatory framework for the HIPAA individual market Federal requirements and addressing the requirements for hospital indemnity and other fixed indemnity insurance to qualify as an excepted benefit in the individual market.[56] The initial HIPAA individual market fixed indemnity excepted benefits coverage regulation, which was effective until July 27, 2014, provided an exemption from the Federal individual market consumer protections and requirements for comprehensive coverage if the hospital indemnity or other fixed indemnity insurance provided benefits under a separate policy, certificate, or contract of insurance and met the noncoordination-of-benefits requirements outlined in the HHS group market excepted benefits regulations.[57]

Following issuance of the Departments' January 24, 2013 FAQ,[58] State insurance regulators and industry groups representing health insurance issuers expressed concerns that prohibiting hospital indemnity and other fixed indemnity insurance from payment on a per-service basis to qualify as an excepted benefit could limit consumer access to an important supplemental coverage option.[59] Based on this feedback, HHS announced in an FAQ released in January 2014 that it intended to propose amendments to the individual market fixed indemnity excepted benefits coverage regulation to allow hospital indemnity or other fixed indemnity insurance sold in the individual market to be considered an excepted benefit if four conditions were met.[60] First, such coverage would be sold only to individuals who have other health coverage that is MEC, within the meaning of section 5000A(f) of the Code. Second, no coordination between the provision of benefits and an exclusion of benefits under any other health coverage would be permitted. Third, benefits would be paid in a fixed dollar amount regardless of the amount of expenses incurred and without regard to whether benefits are provided with respect to an event or service under any other health insurance coverage. Finally, a notice would have to be prominently displayed to inform policyholders that the coverage is not MEC and would not satisfy the individual shared responsibility requirements of section 5000A of the Code. HHS explained that if these proposed revisions were implemented, hospital indemnity or other fixed indemnity insurance in the individual market would no longer have to pay benefits solely on a per-period basis to qualify as an excepted benefit.

In the proposed rule, titled "Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond" (2014 proposed rule), HHS proposed to amend the criteria in 45 CFR 148.220 for fixed indemnity insurance to be treated as an excepted benefit in the individual market.[61] Consistent with the framework outlined in the January 2014 FAQ, the amendments proposed to eliminate the requirement that individual market fixed indemnity excepted benefits coverage must pay benefits only on a per-period basis (as opposed to a per-service basis) and instead proposed to require, among other things, that it be sold only as secondary to other health coverage that is MEC to qualify as an excepted benefit.[62]

On July 28, 2014, in the rule titled "Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond" (2014 final rule), HHS finalized the proposed amendments to 45 CFR 148.220(b)(4) with some modifications. Pursuant to the finalized amendments, hospital indemnity or other fixed indemnity insurance in the individual market may qualify as fixed indemnity excepted benefits coverage if payments are made on a per-period and/or per-service basis subject to several additional requirements that do not apply to fixed indemnity excepted benefits coverage in the group market.[63] Under 45 CFR 148.220(b)(4)(i), to qualify as excepted benefits coverage, benefits under an individual market hospital indemnity or other fixed indemnity insurance policy may only be provided to individuals who attest in their application that they have other health coverage that is MEC within the meaning of section 5000A(f) of the Code, or that they are treated as having MEC due to their status as a bona fide resident of any possession of the United States pursuant to section 5000A(f)(4)(B) of the Code.[64] Further, to qualify as an excepted benefit, 45 CFR 148.220(b)(4)(iv) outlines specific notice language that must be prominently displayed in the application materials for individual market hospital indemnity or other fixed indemnity insurance. Finally, consistent with the group market fixed indemnity excepted benefits coverage regulations, 45 CFR 148.220(b)(4)(ii) implements the statutory noncoordination standard and requires that there is no coordination between the provision of benefits under the individual market fixed indemnity excepted benefits insurance policy and an exclusion of benefits under any other health coverage.

HHS made these changes in the 2014 final rule for two reasons. First, as stated previously, interested parties, including State insurance regulators and industry groups representing health insurance issuers, communicated to HHS that fixed indemnity plans that paid benefits on a per-service basis were widely available as a complement to comprehensive coverage in the group and individual markets. The National Association of Insurance Commissioners (NAIC) also expressed that State insurance regulators believed fixed indemnity plans that paid benefits on a per-service basis provided consumers an important supplemental coverage option by helping consumers that purchase MEC pay for out-of-pocket costs.[65]

[55] 81 FR 75316 at 75317 (October 31, 2016).

[56] 62 FR 16985 at 16992 and 17004 (April 8, 1997).

[57] *Id.*; 45 CFR 146.145(b)(4)(ii)(B) and (C).

[58] Frequently Asked Questions about Affordable Care Act Implementation (Part XI) (Jan. 24, 2013), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xi.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs11*.

[59] While the FAQ only addressed fixed indemnity insurance sold in the group market, the same statutory framework and legal analysis also applies to hospital indemnity and fixed indemnity insurance sold in the individual market.

[60] Frequently Asked Questions about Affordable Care Act Implementation (Part XXVIII) and Mental Health Parity Implementation (Jan. 9, 2014), Q11, available at: *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xviii.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18*.

[61] 79 FR 15807 at 15818–15820, 15869 (March 21, 2014).

[62] *Id.*

[63] 79 FR 30239 (May 27, 2014).

[64] As discussed later in this section and in section III.B.2 of this preamble, the U.S. Court of Appeals for the District of Columbia vacated the requirement at 45 CFR 148.220(b)(4)(i) that an individual attest to having MEC prior to purchasing a hospital indemnity or other fixed indemnity policy in order for the policy to qualify as an excepted benefit. *Central United Life Insurance Company* v. *Burwell*, 827 F.3d 70 (D.C. Cir. 2016).

[65] National Association of Insurance Commissioners (2013). "Letter to Secretaries of Labor, Treasury, and Health and Human Services," available at: *https://naic.soutronglobal.net/Portal/Public/en-GB/RecordView/Index/23541*. ("State regulators believe hospital and other fixed indemnity coverage with variable fixed amounts based on service type could provide important options for consumers as supplemental coverage.

Second, beginning in 2014, most consumers were required to have MEC to avoid being subject to an individual shared responsibility payment under section 5000A of the Code. HHS adopted the MEC attestation requirement to prevent fixed indemnity excepted benefits coverage in the individual market from being offered as a substitute for comprehensive coverage while also accommodating the concerns of interested parties who supported allowing fixed indemnity excepted benefits coverage in the individual market to pay benefits on a per-service basis, rather than only on a per-period basis.[66] However, in its 2016 decision in *Central United Life Insurance Company* v. *Burwell,* the U.S. Court of Appeals for the District of Columbia invalidated the requirement at 45 CFR 148.220(b)(4)(i) that an individual must attest to having MEC prior to purchasing fixed indemnity excepted benefits coverage in the individual market.[67] The Court did not engage in a severability analysis to determine whether HHS would have intended to leave the remaining provisions of the regulation in place, and left intact the language permitting fixed indemnity excepted benefits coverage in the individual market to provide benefits on a per-service basis.

E. Tax Treatment and Substantiation Requirements for Amounts Received From Fixed Indemnity Insurance and Certain Other Arrangements

As part of the 2023 proposed rules, the Treasury Department and the IRS proposed amendments to 26 CFR 1.105–2. For the reasons that follow, the Treasury Department and the IRS are not finalizing the proposed amendments at this time.

Hospital indemnity or other fixed indemnity insurance, as well as coverage only for a specified disease or illness, generally are considered "accident or health insurance" under sections 104, 105, and 106 of the Code, regardless of whether they are "excepted benefits" as defined in section 9832(c) of the Code. Premiums paid by an employer (including by salary reduction pursuant to section 125 of the Code) for accident or health insurance are excluded from an employee's gross income under section 106(a) of the Code. The Treasury Department and the IRS also have recognized the ability of employers and employees to agree to include them in employees' gross income notwithstanding section 106(a) of the Code.[68]

Amounts received through accident or health insurance are excluded from an employee's gross income under section 104(a)(3) of the Code if the premiums were paid on an after-tax basis. However, amounts received are included in an employee's gross income if the amounts are attributable to contributions by an employer that were excluded from the employee's gross income under section 106(a) of the Code. Whether amounts received by an employee through accident or health insurance are excluded from an employee's gross income where the premiums or contributions were paid on a pre-tax basis is determined under section 105. Section 105(a) of the Code provides that such amounts are included in gross income except as otherwise provided in section 105 of the Code. Section 105(b) of the Code excludes such amounts from gross income amounts if they are paid to reimburse the employee's expenses for medical care (as defined in section 213(d) of the Code). Under 26 CFR 1.105–2, this means the exclusion "applies only to amounts which are paid specifically to reimburse the taxpayer for expenses incurred by him for the prescribed medical care."[69]

The 2023 proposed amendments to 26 CFR 1.105–2 would provide that the exclusion from gross income under section 105(b) of the Code does not apply to amounts that are paid without regard to the amount of incurred medical expenses as defined in section 213(d) of the Code. The proposed amendments also would clarify that, consistent with guidance issued by the Treasury Department and the IRS relating to certain specific types of health plans, the substantiation requirements for qualified medical expenses apply to reimbursements under all types of accident and health plans.[70] Finally, the proposed amendments would update several cross-references in 26 CFR 1.105–2 to reflect statutory changes since the rules were issued in 1956.[71]

The Treasury Department and the IRS issued the proposed amendments because uncertainty regarding the exclusion under section 105(b) of the Code has resulted in inconsistent treatment by taxpayers of benefits under different types of accident and health plans and has encouraged some taxpayers to apply the exclusion to situations where the amount or even the existence of medical expenses is doubtful. The Treasury Department and the IRS also are concerned that uncertainty regarding the related Federal Insurance Contributions Act (FICA)[72] and Federal Unemployment Tax Act (FUTA)[73] exclusions, and the Federal income tax withholding rules,[74] has resulted in instances where no FICA, FUTA, or Federal income taxes are withheld from or paid with respect to taxable benefits from accident and health plans and policies by either employers or payors. Although these issues are not limited to fixed indemnity plans and policies, the Treasury Department's and the IRS's concerns have recently escalated after identifying an increasing number of arrangements, some involving fixed indemnity plans and policies, that distribute cash benefit payments, purportedly for medical expenses, even if any expenses incurred may already have been reimbursed through other coverage, or participants do not incur any medical expenses within the meaning of section 213(d) of the Code. In some cases, no medical expenses are incurred and participants simply complete certain health-related activities. Benefit payments from such accident and health plans that are not made on account of medical expenses

Consumers who purchase comprehensive coverage that meets the definition of 'minimum essential coverage' may still wish to buy fixed indemnity coverage to help meet out-of-pocket medical and other costs.").

[66] 79 FR 30239 at 30255 (May 27, 2014).

[67] 827 F.3d 70 (D.C. Cir. July 1, 2016).

[68] *See, for example,* IRS Rev. Rul. 2004–55, which concludes that long-term disability benefits received by an employee who has irrevocably elected, prior to the beginning of the plan year, to have the coverage paid by the employer on an after-tax basis for the plan year in which the employee becomes disabled are attributable solely to after-tax employee contributions and are excludable from the employee's gross income under section 104(a)(3) of the Code.

[69] Additionally, an employer-provided accident or health insurance policy or plan that reimburses an employee for any expenses incurred for medical care is a group health plan subject to section 4980B of the Code, regardless of whether the reimbursements are included in an employee's income under section 105(a) of the Code or excluded under section 104(a)(3) or 105(b) of the Code. In contrast, a policy or plan that does not reimburse an employee for any expenses incurred for medical care is not a group health plan subject to section 4980B of the Code (and section 105(b) of the Code cannot apply to it).

[70] *See, for example,* 84 FR 28888, 28917 (June 20, 2019) (describing substantiation requirements for employer-sponsored health reimbursement arrangements); *see also* Q44–55 of IRS Notice 2017–67, 2017–47 IRB 517; Prop. Treas. Reg. § 1.125–6(b)(4) (2007); IRS Notice 2002–45, 2002–2 CB 93.

[71] The current rules reference section 105(d) of the Code, which has been repealed. The rules also reference the definition of a dependent in section 152(f) of the Code which may, in some circumstances, not include children up to the age of 26 that must be eligible to enroll in a group health plan or group or individual health insurance coverage under section 2714 of the PHS Act (which is incorporated by reference in section 9815 of the Code) if the plan or coverage makes available dependent coverage of children.

[72] Subtitle C, chapter 21 of the Code.

[73] Subtitle C, chapter 23 of the Code.

[74] Subtitle C, chapter 24 of the Code.

incurred generally would not qualify for exclusion from gross income, FICA, FUTA, or Federal income tax withholding.

The Treasury Department and the IRS received comments in support of and in opposition to the proposed amendments to 26 CFR 1.105–2. Commenters who opposed the proposed amendments primarily argued that the exclusion under section 105(b) of the Code should apply with respect to the amount of any medical expenses associated with the health-related event that precipitates payments under accident or health insurance, even if the amount paid is determined without regard to the amount of actual medical expenses incurred (as is required for hospital indemnity or other fixed indemnity insurance to be considered an excepted benefit). These commenters generally argued that only the amount in excess of the medical expenses associated with the health-related event should be included in gross income.

The preamble to the 2023 proposed rules noted that, if the proposed amendments to 26 CFR 1.105–2 were finalized, taxpayers would need to consider the impact the proposal would have on determinations of whether amounts received under accident and health plans constitute wages for employment tax and income tax withholding purposes. Many commenters responded that the proposed amendments would, if finalized, prompt the need for additional guidance regarding collecting and paying employment taxes on some or all of the amounts paid through accident or health insurance that are not excluded from gross income, and proper reporting of such amounts on the employee's Form W–2. Commenters also requested further clarification on how incurred medical expenses must be substantiated.

The Treasury Department and the IRS intend to address these issues in more detail in future guidance. Accordingly, to provide more time to study the issues and concerns raised by commenters, the Treasury Department and the IRS are not finalizing the proposed amendments to 26 CFR 1.105–2 at this time. No inference should be drawn regarding whether or the extent to which the Treasury Department or the IRS agree with any comments on the scope of section 105(b) of the Code based on this decision.

IRS compliance efforts regarding the exclusion from gross income under section 105(b) of the Code will continue to assist taxpayers to satisfy their existing tax responsibilities. Employers are reminded that amounts received through accident or health insurance are not taxable if premiums for the coverage are paid on an after-tax basis, thereby avoiding many of the practical concerns relating to benefits that do not meet the criteria to be excluded from gross income. The Treasury Department and IRS understand that is how most premiums for hospital indemnity or other fixed indemnity insurance are paid.

II. Promoting Access to High-Quality, Affordable, and Comprehensive Coverage

The Departments recognize that STLDI can provide temporary health coverage for individuals who are experiencing brief periods without comprehensive coverage (for example, due to application of a waiting period for employer coverage). They also recognize that fixed indemnity excepted benefits coverage can provide consumers with income replacement that can be used to cover out-of-pocket expenses not covered by comprehensive coverage or to defray non-medical expenses (for example, mortgage or rent) upon the occurrence of a health-related event. Both STLDI and fixed indemnity excepted benefits coverage generally provide limited benefits at lower premiums than comprehensive coverage,[75] and enrollment is typically available at any time (sometimes subject to medical underwriting) rather than being restricted to open and special enrollment periods. However, the Departments are concerned about the financial and health risks that consumers face if they use either form of coverage as a substitute for comprehensive coverage, particularly as a long-term substitute. Consumers who do not understand key differences between STLDI, fixed indemnity excepted benefits coverage, and comprehensive coverage may unknowingly take on significant financial and health risks if they purchase STLDI or fixed indemnity excepted benefits coverage under the misapprehension that such products provide comprehensive coverage. Consumer confusion can be exacerbated when the products are designed in ways that resemble comprehensive coverage. As discussed further in this section II of this preamble, given significant changes in the legal landscape and market conditions since the Departments last addressed STLDI and fixed indemnity excepted benefits coverage, and the low value that STLDI and fixed indemnity excepted benefits coverage provide to some consumers when used as a substitute for comprehensive coverage, the Departments have determined that it is necessary and appropriate to amend the existing Federal regulations governing both types of coverage to more clearly distinguish them from comprehensive coverage and increase consumer awareness of coverage options that include the full range of Federal consumer protections and requirements.

A. Access to Affordable Coverage

In the preamble to the 2018 final rules, the Departments explained the decision to amend the definition of STLDI to expand the initial term and total duration of such policies by citing STLDI as an important means to provide more affordable coverage options and more choices for consumers.[76] The Departments cited a 21 percent increase in individual health insurance coverage premiums between 2016 and 2017, and a 20 percent decrease in average monthly enrollment for individuals who did not receive PTC, along with a 10 percent overall decrease in monthly enrollment during the same period.[77] Additionally, the Departments noted that in 2018 about 26 percent of enrollees (living in 52 percent of counties) had access to just one issuer on the Exchange.[78]

Since the publication of the 2018 final rules, comprehensive coverage for individuals has generally become more accessible and affordable. For example, a study examining issuer participation trends from 2014 to 2021 in every county in the United States found that the number of consumers with multiple issuer options for individual health insurance coverage on the Exchanges has grown consistently since 2018. In 2021, 78 percent of enrollees (living in 46 percent of counties) had a choice of three or more health insurance issuers, up from 67 percent of enrollees in 2020, 58 percent of enrollees in 2019, and 46 percent of enrollees in 2018. Only 3

[75] Although it is typically true that the unsubsidized premium price for comprehensive coverage is greater than STLDI or fixed indemnity excepted benefits coverage, consistent with the greater level of benefits provided under comprehensive coverage, *see* the additional discussion in this section II of this preamble regarding the availability of financial subsidies for eligible individuals to reduce the premium and out-of-pocket costs for comprehensive coverage purchased on an Exchange.

[76] 83 FR 38212 at 38217 (October 2, 2018).

[77] *Id.* at 38214 (citing CMS (2018). "Trends in Subsidized and Unsubsidized Individual Health Insurance Market Enrollment," available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-2.pdf.*)

[78] *Id.* (citing KFF (2017). "Insurer Participation on ACA Marketplaces, 2014–2018," now available at: *https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021/.*)

percent of enrollees (residing in 10 percent of counties) resided in single-issuer counties in 2021—down from 26 percent of enrollees (residing in 52 percent of counties) in 2018.[79] Issuer participation in the Exchanges has continued to trend positively in recent years, with the average number of issuers offering individual health insurance coverage on the Exchanges per State increasing from 5 in 2021 to 6 in 2024.[80] The Centers for Medicare & Medicaid Services (CMS) reported that a record 21.3 million people enrolled in Exchange coverage during the 2024 Open Enrollment Period, including 5 million consumers (approximately 24 percent of total enrollments) who were new to Exchanges in 2024, and 16.3 million returning customers.[81] Nearly 5 million more consumers signed up for coverage during the 2024 Open Enrollment Period compared to the same period in 2023 (an increase of more than 30 percent). This follows an increase of approximately 13 percent in 2023 and an increase of approximately 21 percent in 2022.[82] The enrollment gains in recent years were influenced by the expansion of PTC subsidies, as first provided under the ARP and then extended through 2025 under the IRA, as discussed in section I.A of this preamble.[83] In an analysis prior to the passage of the IRA, the Congressional Budget Office stated that if the ARP subsidies were made permanent, they would attract 4.8 million new people to the Exchanges each year, and that 2.2 million fewer individuals would be without health insurance, on average, over the period from 2023 through 2032.[84]

Additionally, on October 13, 2022, the Treasury Department and the IRS issued final regulations under section 36B of the Code to provide that affordability of employer-sponsored MEC for family members of an employee is determined based on the employee's share of the cost of covering the employee and those family members, not the cost of covering only the employee (2022 affordability rule).[85] It was estimated that this rule change, aimed at addressing the issue often called the "family glitch," would increase the number of individuals with PTC-subsidized Exchange coverage by approximately 1 million per year for the next 10 years.[86]

These recent and projected enrollment trends and the availability of the enhanced subsidies lessen the accessibility and affordability concerns expressed by the Departments in the preamble to the 2018 final rules regarding the availability of affordable options for comprehensive coverage, and offer further support for the provisions in these final rules, which are aimed at helping consumers differentiate between comprehensive coverage and other forms of more limited health coverage to decide which option is best for them.

Although access to affordable comprehensive coverage has improved in recent years, the Departments recognize that affordability concerns continue to persist among consumers, including among consumers who are enrolled in comprehensive coverage. A 2022 national survey conducted by the Commonwealth Fund found that 29 percent of people with employer-sponsored coverage and 44 percent of those with coverage purchased in the individual market (including coverage purchased through an Exchange) were underinsured, meaning that their coverage did not provide them with affordable access to health care.[87] As benchmarks for affordability, the study considered whether out-of-pocket costs over the prior 12 months, excluding premiums, were equal to 10 percent or more of household income; out-of-pocket costs over the prior 12 months, excluding premiums, were equal to 5 percent or more of household income for individuals living under 200 percent of the FPL ($27,180 for an individual or $55,500 for a family of four in 2022); or the deductible constituted 5 percent or more of household income. The performance of STLDI products along these affordability dimensions has been proven worse, often to striking degree, as discussed in section II.B of this preamble.

The Departments also recognize that these affordability concerns could be exacerbated when the expanded PTC subsidies under the IRA end in 2025 or if health expenditures (and therefore premiums) continue to grow at a relatively high rate.[88] The Departments are of the view that it is important to ensure consumers have access to a wide range of products that can support access to affordable health care. However, neither STLDI nor fixed indemnity excepted benefits coverage represent a complete solution to larger issues of affordable access to health care and health coverage, and current marketing practices and benefit designs that mimic comprehensive coverage exacerbates affordability and accessibility concerns. Consumers who enroll in these plans as a substitute for comprehensive coverage or under the misapprehension that STLDI and fixed indemnity excepted benefits coverage are a lower-cost equivalent to comprehensive coverage are at risk of being exposed to significant financial liability in the event of a costly or unexpected health event, often without knowledge of the risk associated with such coverage.

B. Risks to Consumers

As noted in the introduction to this section II of this preamble, the limitations on benefits and coverage under STLDI or fixed indemnity excepted benefits coverage may allow some issuers to offer such coverage at lower monthly premiums than comprehensive coverage. The Departments are concerned about additional costs to consumers who enroll in STLDI or fixed indemnity excepted benefits coverage and incur medical expenses that are not covered by such coverage. The typical limits on coverage provided by STLDI and fixed indemnity excepted benefits coverage can lead to more and higher uncovered medical bills than consumers enrolled

[79] McDermott, Daniel and Cynthia Cox (2020). "Insurer Participation on the ACA Marketplaces, 2014–2021," KFF, available at: *https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021.*

[80] *See* KFF (2024). "Number of Issuers Participating in the Individual Health Insurance Marketplaces, 2014–2024," available at: *https://www.kff.org/other/state-indicator/number-of-issuers-participating-in-the-individual-health-insurance-marketplace.*

[81] *See* CMS (2024). "Marketplace 2024 Open Enrollment Period Report: Final National Snapshot," available at: *https://www.cms.gov/newsroom/fact-sheets/marketplace-2024-open-enrollment-period-report-final-national-snapshot.*

[82] *See* CMS (2023). "Health Insurance Marketplaces, 2023 Open Enrollment Report," available at: *https://www.cms.gov/files/document/health-insurance-exchanges-2023-open-enrollment-report-final.pdf.*

[83] Although unsubsidized premiums for 2023 increased on average between 2.2 percent and 4.7 percent compared to the previous year, after 4 years of declines, the expanded PTC subsidies under the IRA largely shielded many consumers from these premium increases. *See* Ortaliza, Jared, Justin Lo, Krutika Amin, and Cynthia Cox (2022). "How ACA Marketplace Premiums Are Changing By County in 2023," KFF, available at: *https://www.kff.org/private-insurance/issue-brief/how-aca-marketplace-premiums-are-changing-by-county-in-2023.*

[84] Congressional Budget Office (2022). "Letter from Phillip L. Swagel to Rep. Mike Crapo, "Re: Health Insurance Policies," available at: *https://www.cbo.gov/system/files?file=2022-07/58313-Crapo_letter.pdf.*

[85] 87 FR 61979 (October 13, 2022).

[86] *Id.* at 61999.

[87] Collins, Sara, Lauren Haynes, and Relebohile Masitha (2022). "The State of U.S. Health Insurance in 2022: Findings from the Commonwealth Fund Biennial Health Insurance Survey," Commonwealth Fund, available at: *https://www.commonwealthfund.org/publications/issue-briefs/2022/sep/state-us-health-insurance-2022-biennial-survey.*

[88] Regarding trends in national health expenditure, *see* CMS (2023). "NHE Fact Sheet," available at: *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.*

in comprehensive coverage would incur, exposing consumers with STLDI or fixed indemnity excepted benefits coverage to greater financial risk.[89] Healthy consumers who enroll in STLDI or fixed indemnity excepted benefits coverage as an alternative to comprehensive coverage may not realize their STLDI or fixed indemnity excepted benefits coverage excludes or limits coverage for preexisting conditions (including conditions the consumer did not know about when they enrolled), or conditions contracted after enrollment,[90] such as COVID–19, as discussed in this section and in section V.B.2.a.

Additionally, a consumer enrolled in STLDI may discover that a newly-diagnosed medical condition is categorized as a preexisting condition, and related medical expenses will not be covered by, or will be only partially covered by, their STLDI policy.[91] For example, a consumer in Illinois who was diagnosed with Stage IV cancer a month *after* enrolling in STLDI was denied coverage for treatment by the STLDI issuer, both for treatments that led to his successful remission and for a potentially life-saving bone marrow transplant. In his case, the issuer of his STLDI policy determined that his cancer was a preexisting condition because he had disclosed experiencing back pain of undiagnosed cause to the broker who sold him his STLDI policy—leaving him with $800,000 of medical debt and without meaningful health coverage as he continued to fight his illness.[92]

The financial risk for consumers enrolled in STLDI increases with the length of their policy, as the longer consumers are enrolled in STLDI, the more likely they are to incur costs that are not covered. This is especially the case for consumers who encounter newly diagnosed conditions or have a significant medical event while enrolled in STLDI. Researchers found that the maximum out-of-pocket health care spending limit for STLDI was on average nearly three times that of comprehensive coverage in 2020.[93] A 2020 report found that over 60 percent of the STLDI policies surveyed had a maximum out-of-pocket limit greater than the $7,900 limit that was permitted for self-only comprehensive coverage in 2019, and 15 percent had limits in excess of $15,000; as is typical for STLDI, these limits apply only to the coverage period, which in some cases was only 6 months, compared to the annual limits required under the ACA for comprehensive coverage.[94] Consumers enrolled in STLDI who ultimately require medical care are more likely to incur higher out-of-pocket costs than if they had enrolled in comprehensive coverage.[95] Refer to section V.B.2.c of this preamble for additional discussion of the financial risks to consumers.

As noted in section I.D of this preamble, consumers who enroll in fixed indemnity excepted benefits coverage as an alternative to comprehensive coverage bear similar risk and exposure to significant out-of-pocket expenses due to their health care costs exceeding the fixed cash benefit to which they may be entitled, if benefits are even provided at all for their illness or injury. Comments received in response to the 2023 proposed rules affirmed the Departments' concerns by offering several examples of consumer risk and exposure resulting from enrollment in fixed indemnity insurance. For example, one commenter described a fixed indemnity plan that advertised that it would pay $25 for a doctor visit, $100 for a diagnostic exam, and $300 for neonatal intensive care, and contrasted those benefits to one hospital's pricing schedule for NICU service, Level 4. The commenter observed that a consumer with such fixed indemnity insurance alone could still face $8,500 daily for NICU services. Another commenter stated that indemnity plans that are structured to pay various dollar amounts for different services appear very similar to comprehensive insurance, even though they offer much less coverage.

Consumers who enroll in STLDI and fixed indemnity excepted benefits coverage and do not also have comprehensive coverage may experience financial hardship when their medical bills are unaffordable.[96] Notably, the protections against balance billing and out-of-network cost sharing for certain out-of-network services established under the No Surprises Act, which are intended to shield consumers from surprise bills that can result in medical debt,[97] do not apply to STLDI or fixed indemnity excepted benefits coverage.[98] Because STLDI is typically subject to medical underwriting and is not guaranteed renewable, consumers enrolled in STLDI in lieu of comprehensive coverage may be unable to renew their STLDI policy at the end of the coverage period. These consumers therefore face the risk of being uninsured until they are eligible to purchase comprehensive coverage in the individual market during an open

[89] Palanker, Dania, JoAnn Volk, and Kevin Lucia (2018). "Short-Term Health Plan Gaps and Limits Leave People at Risk," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2018/short-term-health-plan-gaps-and-limits-leave-people-risk.* (Describing STLDI marketing materials that list coverage limits that would fall far short of typical costs to a consumer, including $1,000 a day for hospital room and board coverage, $1,250 a day for the intensive care unit, $50 a day for doctor visits while in the hospital, $100 a day for inpatient substance abuse treatment, and $250 for ambulance transport).

[90] *See* Williams, Jackson (2022). "Addressing Low-Value Insurance Products With Improved Consumer Information: The Case of Ancillary Health Products," National Association of Insurance Commissioners, *Journal of Insurance Regulation*, available at: *https://content.naic.org/sites/default/files/cipr-jir-2022-9.pdf.*

[91] *See* Lueck, Sarah (2018). "Key Flaws of Short-Term Health Plans Pose Risks to Consumers," Center on Budget and Policy Priorities, available at: *https://www.cbpp.org/research/health/key-flaws-of-short-term-health-plans-pose-risks-to-consumers. See also* Hall, Mark and Michael McCue (2022). "Short-Term Health Insurance and the ACA Market," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2022/short-term-health-insurance-and-aca-market. See also* Partnership to Protect Coverage (2021). "Under-Covered: How 'Insurance-Like' Products are Leaving Patients Exposed," available at: *https://www.nami.org/NAMI/media/NAMI-Media/Public%20Policy/Undercovered_Report_03252021.pdf.*

[92] Partnership to Protect Coverage (2021). "Under-Covered: How 'Insurance-Like' Products are Leaving Patients Exposed," available at: *https://www.nami.org/NAMI/media/NAMIMedia/Public%20Policy/Undercovered_Report_03252021.pdf.*

[93] Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-term Limited-duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[94] *Id. See also* Palanker, Dania, Kevin Lucia, and Emily Curran (2017). "New Executive Order: Expanding Access to Short-Term Health Plans Is Bad for Consumers and the Individual Market," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2017/new-executive-order-expanding-access-short-term-health-plans-bad-consumers-and-individual.* ("When considering the deductible, the best-selling plans have out-of-pocket maximums ranging from $7,000 to $20,000 for just three months of coverage. In comparison, the ACA limits out-of-pocket maximums to $7,150 for the entire [2017 calendar] year.").

[95] *Id.*

[96] Unaffordable medical debt increasingly impacts members of disadvantaged and marginalized communities. *See* Lopes, Lunna, Audrey Kearney, Alex Montero, Liz Hamel, and Mollyann Brodie (2022). "Health Care Debt In The U.S.: The Broad Consequences Of Medical And Dental Bills," KFF, available at: *https://www.kff.org/health-costs/report/kff-health-care-debt-survey. See also* Himmelstein, David, Samuel Dickman, Danny McCormick, David Bor, Adam Gaffney, and Steffie Woolhandler (2022). "Prevalence and Risk Factors for Medical Debt and Subsequent Changes in Social Determinants of Health in the US," *JAMA Network Open*, Volume 5, Issue 9, available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796358.*

[97] Families USA (2019). "Surprise Medical Bills, Results from a National Survey," available at: *https://familiesusa.org/wp-content/uploads/2019/11/Surprise-Billing-National-Poll-Report-FINAL.pdf.*

[98] *See* 26 CFR 54.9816–2T, 29 CFR 2590.716–2(b), and 45 CFR 149.20(b).

enrollment or when a special enrollment period occurs. It is therefore critical for consumers to understand, prior to purchase, that STLDI serves better as a bridge between different sources of comprehensive coverage than as an alternative to comprehensive coverage, and that choosing to substitute STLDI for comprehensive coverage may reduce access to coverage. Similarly, as noted in section I.D of this preamble, consumers need to understand, prior to purchase, that fixed indemnity excepted benefit coverage serves best as an income replacement policy [99] that supplements comprehensive coverage by providing financial assistance, rather than serving as an alternative to comprehensive coverage.

In the preamble to the 2018 final rules, the Departments stated that individuals who purchased STLDI would potentially experience improved health outcomes and have greater protection from catastrophic health care expenses than if those individuals were uninsured.[100] However, experience with the COVID–19 public health emergency (PHE) [101] has prompted the Departments to reassess the degree of protection generally afforded by STLDI and fixed indemnity excepted benefits coverage, and to reassess the value of a framework that instead encourages uninsured individuals to purchase comprehensive coverage. Enrollees in STLDI with COVID–19 typically face significant limitations on coverage for COVID–19 related treatments, and high out-of-pocket expenses.[102] In addition, neither STLDI nor fixed indemnity excepted benefits coverage was subject to requirements under section 6001 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020), as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020), to cover COVID–19 diagnostic testing, without cost sharing, furnished during the COVID–19 PHE; or the requirement under section 3203 of the CARES Act to cover qualifying coronavirus preventive services, including COVID–19 vaccines, without cost sharing.[103] Instead, both of these important coverage expansions enacted by Congress as part of the nation's response to the COVID–19 PHE applied only to comprehensive coverage. Any coverage by STLDI of (or, with respect to fixed indemnity excepted benefits coverage, benefits provided related to) COVID–19 diagnostic testing or vaccines was subject to the discretion of individual issuers of these policies and applicable State law. Notably, the Health Resources and Services Administration's COVID–19 Coverage Assistance Fund, which reimbursed eligible health care providers for providing COVID–19 vaccines to underinsured individuals, included enrollees in STLDI and excepted benefits coverage within the definition of underinsured.[104] The CARES Act also amended the definition of "uninsured individual" in Social Security Act section 1902(ss) to include individuals enrolled only in STLDI. Even individuals enrolled in STLDI or fixed indemnity excepted benefits coverage who are generally healthy are at risk of needing health care, and thus at risk of incurring unaffordable medical bills at any time. The COVID–19 PHE underscored the unpredictability of when the need for medical care will arise, and the importance of encouraging individuals to enroll in comprehensive coverage.

The Departments have also become aware of potentially deceptive or aggressive marketing of STLDI and fixed indemnity excepted benefits coverage to consumers who may be unaware of the coverage limits of these plans or the availability of Federal subsidies that could reduce the costs of premiums and out-of-pocket health care expenditures for comprehensive coverage purchased

[99] As an income replacement policy, the policyholder of a fixed indemnity excepted benefits coverage plan typically has broad discretion in how to use the fixed cash benefits provided, including but not limited to payment for medical expenses not covered by comprehensive coverage (for example, deductibles, coinsurance, copays) or to defray non-medical costs (for example, mortgage or rent).

[100] 83 FR 38212, 38229 (October 2, 2018).

[101] On January 31, 2020, HHS Secretary Alex M. Azar II declared that as of January 27, 2020, a nationwide public health emergency exists as a result of the 2019 novel coronavirus (COVID–19). *See* HHS Administration for Strategic Preparedness and Response (January 31, 2020). "Determination That A Public Health Emergency Exists," available at: *https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx*. This declaration was last renewed by HHS Secretary Xavier Becerra on October 13, 2022, following previous renewals on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 20, 2021, October 18, 2021, January 14, 2022, April 12, 2022, and July 15, 2022. *See* "HHS Administration for Strategic Preparedness and Response, Renewal of Determination That A Public Health Emergency Exists," available at: *https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx*. On January 30, 2023, and February 9, 2023, the Biden-Harris Administration announced that it intended to end the PHE at the end of the day on May 11, 2023. *See* Executive Office of the President, Office of Management and Budget (January 30, 2023). "Statement of Administration Policy: H.R. 382 and H.J. Res. 7," available at: *https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf;* HHS Secretary Xavier Becerra (February 9, 2023). "Letter to U.S. Governors from HHS Secretary Xavier Becerra on renewing COVID–19 Public Health Emergency (PHE)," available at: *https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html*. The PHE ended at the end of the day on May 11, 2023.

[102] *See, for example,* Curran, Emily, Kevin Lucia, JoAnn Volk, and Dania Palanker (2020). "In the Age of COVID–19, Short-Term Plans Fall Short for Consumers," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2020/age-covid-19-short-term-plans-fall-short-consumers*. This study found that STLDI policies provide less financial protection than comprehensive coverage if an enrollee needs treatment for COVID–19. The study found that among the 12 brochures reviewed for STLDI policies being sold in Georgia, Louisiana, and Ohio, 11 excluded nearly all coverage for prescription drugs, with some providing limited coverage of inpatient drugs. The study further found that STLDI imposed high cost sharing, with deductibles ranging from $10,000 to $12,500 (which did not count toward the enrollees' maximum out-of-pocket costs) and that enrollees may be required to meet separate deductibles for emergency room treatment, forcing some enrollees to face out-of-pocket costs of more than $30,000 over a 6-month period. Additionally, the study found that STLDI did not cover services related to pre-existing conditions.

[103] Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 71142, 71173 (Nov. 6, 2020); *See also* Departments of the Treasury, Labor, and Health and Human Services. "FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, Q1," (April 11, 2020), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-42.pdf* and *https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf* (FAQs Part 42); "FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 50," (October 4, 2021), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-50.pdf* and *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-50.pdf* (FAQs Part 50); "FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation," (Jan. 10, 2022), available at: *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf* (FAQs Part 51); FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 52" (February 4, 2022), available at: *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-52.pdf* and *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-52.pdf* (FAQs Part 52); and "FAQs about Families First Coronavirus Response Act, Coronavirus Aid, Relief, and Economic Security Act and Health Insurance Portability and Accountability Act Implementation Part 58" (March 29, 2023), available at: *https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-58* and *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-58.pdf* (FAQs Part 58). Note that the COVID–19 PHE ended on May 11, 2023.

[104] Underinsured individuals are defined for this purpose as having a health plan that either does not include COVID–19 vaccine administration as a covered benefit or covers COVID–19 vaccine administration but with cost sharing. *See* Health Resources and Services Administration. "FAQs for The HRSA COVID–19 Coverage Assistance Fund," available at: *https://www.hrsa.gov/provider-relief/about/covid-19-coverage-assistance/faq*.

through an Exchange.[105] A recent study that engaged in covert testing of health insurance sales representatives found evidence of deceptive marketing practices by agents and brokers who omitted or misrepresented information about the products they were selling.[106] For example, during a phone transaction, a sales representative told the consumer that they were purchasing a comprehensive health insurance plan, but instead sold the consumer two limited benefit insurance plans. During the exchange, the consumer repeatedly informed the sales representative that they had diabetes and had recently been seeking treatment for the condition. However, the application filled out by the sales representative on the consumer's behalf stated that consumer had not been treated for or diagnosed with diabetes for the past 5 years. In another phone transaction, the sales representative enrolled the consumer in a benefit association offering a limited benefit indemnity insurance plan. The representative would not provide the consumer with documentation describing the plan prior to enrollment and stated that the consumer had to purchase the plan on the day of the call if they wanted to be guaranteed the quoted price. The Departments note that these concerns are not limited to individual market consumers considering STLDI or fixed indemnity excepted benefits coverage. Reports that employers are increasingly offering fixed indemnity coverage alongside a plan that offers only a very limited set of primary or preventive care benefits (or in some cases, as the only form of health coverage) have also raised concerns with respect to consumers who obtain this health coverage through their employers.[107]

Consumers who are unaware of the coverage limitations of these arrangements, or who are employed by employers who are similarly unaware, can face overwhelming medical costs if they require items and services that are not covered by the very limited group health plan. This is because the fixed indemnity excepted benefits coverage generally provides only fixed cash benefits that may be far lower than the costs of medical services, rather than coverage intended to cover most of the costs of the medical services themselves. For example, a Texas consumer who was enrolled in two forms of health insurance through his employer received a $67,000 hospital bill after he experienced a heart attack. Although he believed he had comprehensive coverage, he learned that his coverage was provided through a group health plan that covered only preventive services and prescription drugs and a fixed indemnity excepted benefits coverage policy that provided a cash benefit of less than $200 per day of hospitalization.[108] Additionally, employers may incur penalties if they erroneously treat fixed indemnity policies as excepted benefits when the policies do not meet the requirements for excepted benefits (for example, when they are not offered as independent, noncoordinated benefits) and fail to comply with applicable group market Federal consumer protections and requirements for comprehensive coverage, such as the requirement to provide participants, beneficiaries, and enrollees with a summary of benefits and coverage that meets applicable content requirements or the prohibition on lifetime and annual dollar limits on essential health benefits.[109]

In light of research revealing significant disparities in health insurance literacy among certain underserved racial and ethnic groups and people with incomes below the FPL,[110] and as further discussed in sections III.A.1 and V.B.2.g of this preamble, the Departments are also concerned that underserved populations may be particularly vulnerable to misleading or aggressive sales and marketing tactics that obscure the differences between comprehensive coverage and STLDI or fixed indemnity excepted benefits coverage, exposing these populations to higher levels of health and financial risks. As noted in Executive Order 13995, the COVID–19 pandemic has "exposed and exacerbated severe and pervasive health and social inequities in America," highlighting the urgency with which such inequities must be addressed.[111] These concerns continue during the time frame when States are unwinding from the Medicaid continuous enrollment condition under the Families First Coronavirus Response Act (FFCRA), which expired on March 31, 2023, under amendments made by the Consolidated Appropriations Act, 2023. Across the country, State agencies are currently in the process of resuming regular eligibility and enrollment operations, which includes conducting full Medicaid and CHIP renewals and terminating coverage for individuals who are no longer eligible.[112] As a result, individuals may have to transition between coverage programs, leaving them vulnerable.[113] The Departments are concerned that those transitioning out of Medicaid coverage may be susceptible to aggressive or deceptive marketing and sales tactics,

[105] Palanker, Dania and Kevin Lucia (2021). "Limited Plans with Minimal Coverage Are Being Sold as Primary Coverage, Leaving Consumers at Risk," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2021/limited-plans-minimal-coverage-are-being-sold-primary-coverage-leaving-consumers-risk.* (Noting that fixed indemnity insurance may be "bundled" with other non-comprehensive insurance products in such a way that "the plans look like comprehensive coverage" while still offering limited benefits). *See also* Palanker, Dania, JoAnn Volk, and Maanasa Kona (2019). "Seeing Fraud and Misleading Marketing, States Warn Consumers About Alternative Health Insurance Products," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/seeing-fraud-and-misleading-marketing-states-warn-consumers-about-alternative-health.*

[106] Government Accountability Office (2020). "Private Health Coverage: Results of Covert Testing for Selected Offerings," available at: *https://www.gao.gov/products/gao-20-634r.*

[107] Young, Christen Linke and Kathleen Hannick (2020). "Fixed Indemnity Coverage is a Problematic Form of "Junk" Insurance," U.S.C.-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance.*

[108] Avila, Jaie (2019). "Show Me Your Bill Helps Wipe Out $70K in Charges After Heart Attack," News 4 San Antonio, available at: *https://news4sanantonio.com/news/trouble-shooters/show-me-your-bill-helps-wipe-out-70k-in-charges-after-heart-attack.*

[109] *See* 26 CFR 54.9815–2715(e); 29 CFR 2590.715–2715(e); 45 CFR 147.200(e). *See also* section 2711 of the PHS Act and section 4980D of the Code.

[110] Edward, Jean, Amanda Wiggins, Malea Hoepf Young, Mary Kay Rayens (2019). "Significant Disparities Exist in Consumer Health Insurance Literacy: Implications for Health Care Reform," *Health Literacy Research and Practice,* available at: *https://pubmed.ncbi.nlm.nih.gov/31768496. See also* Villagra, Victor and Bhumika Bhuva (2019). "Health Insurance Literacy: Disparities by Race, Ethnicity, and Language Preference," *The American Journal of Managed Care,* available at: *https://www.ajmc.com/view/health-insurance-literacy-disparities-by-race-ethnicity-and-language-preference.*

[111] 86 FR 7193 (January 26, 2021).

[112] *See* CMS, Center for Medicaid & CHIP Services (January 5, 2023). Key Dates Related to the Medicaid Continuous Enrollment Condition Provisions in the Consolidated Appropriations Act, 2023, available at: *https://www.medicaid.gov/sites/default/files/2023-01/cib010523_1.pdf.* As a condition of receiving a temporary Federal Medical Assistance Percentage (FMAP) increase under section 6008 of the FFCRA, States were required to maintain enrollment of nearly all Medicaid enrollees. This "continuous enrollment condition" expired on March 31, 2023, under amendments made by the Consolidated Appropriations Act, 2023. States adopted other flexibilities in CHIP and BHP that impacted renewals in those programs during this time.

[113] *See* CMS, Center for Medicaid & CHIP Services (January 27, 2023). "Letter to State Health Officials from Deputy Administrator and Director Daniel Tsai RE: Medicaid Continuous Enrollment Condition Changes, Conditions for Receiving the FFCRA Temporary FMAP Increase, Reporting Requirements, and Enforcement Provisions in the Consolidated Appropriations Act, 2023," available at: *https://www.medicaid.gov/sites/default/files/2023-08/sho23002.pdf.*

and might therefore mistakenly enroll in STLDI or fixed indemnity excepted benefits coverage in lieu of comprehensive coverage.

C. Impact on Risk Pools

At the time the 2018 final rules were issued, the Departments acknowledged that expanding access to STLDI could have potential negative effects on the risk pools for individual health insurance coverage and on individuals who find themselves insufficiently protected by the typically limited benefits of an STLDI policy.[114] However, the Departments were of the view that the affordability and access challenges facing consumers at that time outweighed those potential negative effects and necessitated action to increase access to STLDI to provide an alternative option for individuals who were unable or disinclined to purchase comprehensive coverage.

As discussed earlier in section II.A of this preamble, access to affordable comprehensive coverage has significantly improved since the 2018 final rules were published. However, research based on individual market data for plan year 2020 has substantiated concerns about the negative impact that the shift of healthier individuals from comprehensive coverage to STLDI has on individuals remaining in the risk pools for individual health insurance coverage.[115] Because healthier individuals are more likely to enroll in STLDI than individuals with known medical needs, the extended contract terms and renewal periods of STLDI under the current Federal regulations result in healthier consumers leaving (or opting out of) the risk pools for individual health insurance coverage for extended periods of time. This has resulted in increased premiums for individuals seeking to purchase individual health insurance coverage.[116] For unsubsidized individuals, the costs are borne directly by the consumer, and for subsidized individuals, the costs are borne largely by the Federal Government in the form of increased per capita PTC spending associated with increased individual health insurance coverage premiums. Likewise, reports of fixed indemnity excepted benefits coverage being marketed and sold as an alternative to comprehensive coverage, as discussed in section V.B.2.a of this preamble, raise concerns about the potential for such practices having a similar impact on the risk pools for individual health insurance coverage.

Another study looking at States that have adopted policies that restrict STLDI to shorter durations than allowed under the current Federal regulations found that, from 2018 to 2020, States that restricted or prohibited the sale of STLDI saw fewer consumers enroll in such insurance, were able to keep more healthy people in the individual health insurance coverage market risk pool, and saw a greater decline in average medical costs for enrollees in individual health insurance coverage.[117] The study reported that, as a result, the risk score—a measurement of the relative medical costs expected for the populations covered by comprehensive coverage in each State, both on- and off-Exchange—decreased by 40 percent more in States with more regulation of STLDI than States with less regulation.[118]

In addition to ensuring that consumers can clearly distinguish STLDI from comprehensive coverage, this new evidence provides an additional basis for the Departments' conclusion that it is important to amend the Federal definition of STLDI.

D. Need for Rulemaking

For the reasons described in this section II of this preamble, the Departments are of the view that it is necessary and appropriate to amend the Federal definition of STLDI to ensure that consumers can clearly distinguish STLDI from comprehensive coverage, protect the risk pools and stabilize premiums for individual health insurance coverage, and promote access to affordable comprehensive coverage.

With respect to individual market fixed indemnity excepted benefits coverage, the decision in *Central United Life Ins. Co.* v. *Burwell,* which invalidated the requirement that an individual must attest to having MEC prior to purchasing fixed indemnity excepted benefits coverage in the individual market, and the passage of the Tax Cuts and Jobs Act, which reduced the individual shared responsibility payment to $0 for months beginning after December 31, 2018, increase the likelihood that individuals would purchase fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage. HHS is of the view that these changes necessitate rulemaking with respect to individual market fixed indemnity excepted benefits coverage. Further, while the Departments did not finalize the proposed amendments to the group market fixed indemnity excepted benefits coverage regulations outlined in the 2016 proposed rules, the Departments noted their intention to address fixed indemnity excepted benefits coverage in future rulemaking.[119] The Departments have continued to monitor the impact of these coverage options and remain concerned about the negative impacts of fixed indemnity excepted benefits coverage on consumers when such products are sold as an alternative to comprehensive coverage.

In light of the Departments' ongoing concerns about the numerous negative impacts of STLDI and fixed indemnity excepted benefits coverage being offered as an alternative to comprehensive coverage, as well as the significant changes in market conditions and in the legal landscape since the Departments' last regulatory actions addressing these products, and in consideration of the comments on the 2023 proposed rules received by the Departments, the Departments are finalizing changes to the Federal regulations governing STLDI and addressing notice requirements in the individual and group market regulations related to fixed indemnity excepted benefits coverage. HHS is also finalizing the technical amendments to the individual market fixed indemnity excepted benefits coverage regulation to remove the MEC attestation requirement currently codified at 45 CFR 148.220(b)(4)(i). As further explained in section III.B of this preamble, the Departments are not finalizing the proposed payment standards and noncoordination provisions regarding

[114] 83 FR 38212 at 38218 (August 3, 2018).

[115] *See* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-term Limited-duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[116] *Id.* ("Carrier expectations for the impact of [regulatory actions including the expansion of short-term, limited-duration insurance policies and other loosely regulated insurance and the repeal of the Federal individual shared responsibility payment being reduced to $0] on premiums in the ACA individual market for 2020 are approximately 4 percent in [S]tates that have not restricted the sale or duration of STLD policies . . . Among the [S]tates that have limited the impact of loosely regulated insurance through reinstating an individual mandate or by restricting STLD expansion, carriers have assumed an average premium impact in 2020 due to regulatory actions that is about 5 percent lower than other [S]tates.") As noted in section V.B.2.e of this preamble, this study also found that the few issuers that explicitly included a premium adjustment because of the adoption of the revised Federal definition of STLDI in the 2018 final rules increased premiums by between 0.5 percent and 2 percent in 2020.

[117] *See* Hall, Mark and Michael McCue (2022). "Short-Term Health Insurance and the ACA Market," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2022/short-term-health-insurance-and-aca-market.*

[118] *Id.*

[119] 81 FR 75316 at 75317 (October 31, 2016).

fixed indemnity excepted benefits coverage at this time. The Departments remain concerned about the issues addressed by these proposals, and intend to address these issues in future rulemaking, after additional study and consideration of the concerns raised in comments.

III. Overview of the Final Regulations—The Departments of the Treasury, Labor, and Health and Human Services

A. Short-Term, Limited-Duration Insurance

After considering the public comments, the Departments are finalizing the proposed amendments to the Federal definition of STLDI with some modifications. Under the definition in these final rules, STLDI means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance that has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this definition, a renewal or extension includes the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance. As explained in section III.A.2 of this preamble, in response to comments, the Departments are specifying that for purposes of this definition, if the issuer is a member of a controlled group, a renewal or extension also includes the term of a new STLDI policy, certificate, or contract of insurance issued by any other issuer that is a member of such controlled group. As used in this context, the term "controlled group" means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code, as amended.

These final rules also retain the requirement that STLDI issuers display a notice on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font. As finalized in these final rules, STLDI issuers must use the following updated language for the STLDI consumer disclosure notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

As explained in section III.A.4 of this preamble, in response to comments, the notice adopted in these final rules contains additional specificity, including that STLDI does not have to meet Federal standards for comprehensive coverage and information about finding contact information for State departments of insurance on the NAIC website (*naic.org*).

In response to comments, the Departments are finalizing modified applicability dates. These final rules apply to new STLDI policies sold or issued on or after September 1, 2024. The provisions of the 2018 final rules

continue to apply to STLDI policies sold or issued before September 1, 2024, except that the updated notice provision adopted in these final rules applies to such policies for coverage periods beginning on or after September 1, 2024. As was proposed in the 2023 proposed rules, these final rules are effective 75 days after publication in the **Federal Register**.

1. In General

The Departments received comments generally in support of and generally opposed to the adoption of the STLDI proposals in the 2023 proposed rules. The Departments summarize and respond to comments about the STLDI proposals in the 2023 proposed rules later in this section of the preamble.

Some commenters stated that the 2023 proposed rules were an overreach of the Departments' authority because Congress did not provide an explicit delegation of authority to define the terms "short-term" and "limited-duration." Some commenters expressed concern that the 2023 proposed rules are contrary to congressional intent because Congress specifically determined that certain types of insurance would not be subject to the requirements of the ACA, including STLDI, which is excepted from the definition of individual health insurance coverage. Commenters suggested that the Departments' interpretation is unreasonable because it conflicts with and undermines Congress's express goals for consumers to have access to STLDI plans that are exempt from Federal regulation, to reduce gaps in health insurance and the number of uninsured. One commenter also expressed concern that the Departments' interpretation will increase medical underwriting frequency to every 3 to 4 months leading to more consumers losing coverage. One commenter stated that the Departments' interpretation is unreasonable because it pressures consumers into enrolling in comprehensive coverage to avoid greater financial exposure. Several commenters stated that there is no statutory basis for the Departments to regulate consumer behavior and the Departments have no legal authority to impose burdens or limitations on STLDI, such as a consumer notice. One commenter argued that the Departments lack the authority to implement a shorter maximum allowed length because the proposals are overly broad and will unduly harm consumers. Several commenters stated that the proposed rules are arbitrary, capricious, and not in accordance with law because the Departments rely on factors to justify the new definition that were not relevant to Congress's considerations.

The Departments are not persuaded by these comments. As explained in greater detail in this section III.A.1 of this preamble, these final rules revise the definition for the term "short-term, limited-duration insurance," and set standards to more clearly distinguish STLDI from individual health insurance coverage. These final rules do not regulate consumer behavior. Consumers will continue to have access to STLDI plans that are generally exempt from the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage.[120] As detailed later in this section of this preamble, the Departments have clear authority to promulgate regulations to define STLDI and to pursue the current amendments. The Departments also disagree that the definition in the proposed rules, and as finalized in these rules, is unreasonable, inconsistent with the law, or arbitrary and capricious.

Other commenters stated that the Departments have clear statutory authority under the PHS Act to interpret undefined terms in the PHS Act, ERISA, and the Code,[121] and to promulgate regulations that interpret (or reinterpret) the meaning of "short-term, limited-duration," so long as their interpretation is reasonable. These commenters observed that Congress did not define the term "short-term, limited-duration insurance," and primarily only included a reference to STLDI as an exclusion from individual health insurance coverage.[122] [123] These commenters explained that the Departments must give meaning to the term short-term, limited-duration insurance to distinguish it from individual health insurance coverage.

The Departments disagree with the commenters who questioned the Departments' legal authority to promulgate Federal regulations to define STLDI and distinguish it from individual health insurance coverage. As explained in the preamble to the 2018 final rules,[124] the Departments have clear statutory authority under the Code, ERISA, and the PHS Act to implement those statutes.[125] To determine what is and is not individual health insurance coverage, which is essential to ensure that the Code, ERISA, and the PHS Act function as Congress intended, and to allow enforcement of the rules that apply to individual health insurance coverage, the Departments must give meaning to the term STLDI.[126]

The 2023 proposed rules are faithful to Congress's intent because Congress wanted STLDI to be an option but did not intend STLDI to be a substitute for comprehensive coverage or to pass as comprehensive coverage while avoiding ACA requirements and other Federal consumer protections applicable to comprehensive coverage. Finally, the 2023 proposed rules and these final rules are not designed to limit access to STLDI or pressure consumers into enrolling in comprehensive coverage. Rather, they are designed to, among other things, ensure that consumers can distinguish between STLDI and comprehensive coverage. Congress provided the Secretaries of the Treasury, Labor, and HHS with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act.[127] This includes the authority to issue regulations on STLDI to define it and set standards to distinguish it from individual health insurance coverage.

The Departments' authority to issue regulations that define STLDI and set standards to distinguish it from individual health insurance coverage was also recently affirmed in the D.C.

[120] Neither the proposed rules nor these final rules seek to extend the Federal consumer protections and requirements for comprehensive individual health insurance coverage to STLDI.

[121] *See* section 715 of ERISA and section 9815 of the Code, which incorporate provisions of part A of title XXVII of the PHS Act (generally, sections 2701 through 2728 of the PHS Act) into ERISA and the Code. *See also* section 104 of HIPAA. *See also* sections 505 and 734 of ERISA, sections 2761 and 2792 of the PHS Act, section 1321(a)(1) and (c) of ACA and section 7805 of the Code.

[122] *See* section 2791(b)(5) of the PHS Act (defining "individual health insurance coverage").

[123] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

[124] 83 FR 38212 at 38215 (August 3, 2018).

[125] *See* section 9815 of the Code and section 715 of ERISA, which incorporate provisions of Part A of title XVIII of the PHS Act (generally, sections 2701 through 2728 of the PHS Act) into the Code and ERISA. *See also* section 104 of HIPAA. *See also* section 7805 of the Code, sections 505 and 734 of ERISA, sections 2761 and 2792 of the PHS Act, and section 1321(a)(1) and (c) of the ACA. *See also Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury*, 966 F.3d 782 (D.C. Cir. 2020).

[126] As discussed in footnote 13, the definition of STLDI also has some relevance with respect to certain provisions that apply to group health plans and group health insurance issuers over which the Departments of Labor and the Treasury have jurisdiction.

[127] *See* section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Circuit.[128] In 2020, the D.C. Circuit explicitly considered the Departments' authority to define STLDI as finalized in the 2018 final rules and affirmed the Departments' authority to promulgate such regulations.[129] The D.C. Circuit stated:

> Without further guidance from Congress, we will not place amorphous restrictions on the Departments' authority to define such an open-ended term. It suffices to say that the Departments have the discretion to define STLDI to include policies shorter than the standard policy term.[130]

Furthermore, the decision made clear that Congress gave the Departments "wide latitude" to define STLDI, which includes the flexibility to narrow the definition of STLDI in the future, provided the Departments provide a reasoned explanation for the change.[131] Both the 2023 proposed rules and these final rules provide the Departments' reasoned explanations for the changes to the Federal definition of STLDI. These final rules adopt a revised Federal definition of the term STLDI and set standards to more clearly distinguish STLDI from individual health insurance coverage without placing unreasonable burdens on issuers of STLDI.

The Departments acknowledge that the final rules may be associated with some consumers being subject to medical underwriting more frequently. For example, a consumer who prefers STLDI coverage and chooses to reenroll in STLDI coverage with a different issuer every 4 months may be subject to medical underwriting each time they enroll or renew coverage, whereas under the current rules they could stay in one STLDI policy for a longer duration. However, in the Departments' view, this possibility does not outweigh other potential benefits to consumers of the revised definition of STLDI, in part because consumers face a similar risk under the current rules. Even when enrolled in STLDI coverage that complies with the 2018 final rules, a consumer can be subject to post-claims underwriting and their STLDI coverage may not cover certain health conditions that develop unexpectedly or over time. Yet because the STLDI coverage has a longer maximum duration under current rules, a consumer who remains in STLDI coverage might go without necessary benefits for a longer period of time, forcing the consumer to choose between necessary medical care and high out-of-pocket expenses. Consumers may avoid the potential consequences of more frequent medical underwriting by enrolling in comprehensive coverage subject to Federal consumer protections and requirements.

The definition and standards, as proposed and finalized, apply to health insurance issuers that elect to offer STLDI, and they do not regulate consumer behavior. Issuers will not be prohibited from selling STLDI and consumers may continue to choose to purchase it. The changes to the Federal definition and standards for STLDI will help consumers make more informed purchasing decisions and mitigate the risk that consumers will mistakenly enroll in STLDI as a substitute for comprehensive coverage.

The Departments disagree that the revised Federal definition of STLDI is unreasonable or arbitrary and capricious. As explained in the preamble to the 2023 proposed rules[132] and in the introduction to this section III.A of this preamble, the Federal definition established in these final rules clearly distinguishes STLDI from individual health insurance coverage that is subject to the Federal consumer protections and requirements for comprehensive coverage. Further, the statute does not explicitly denote a required length for STLDI or to what extent the definition of STLDI must vary from the definition of individual health insurance coverage, so the Departments are interpreting and implementing the statute in a manner that distinguishes between STLDI and individual health insurance coverage. Over the last two decades, the Departments have used this discretion to both shorten and lengthen the duration of STLDI as the Departments have deemed appropriate and necessary given the market conditions and legal landscape they were then facing. Beginning in 1997, the Departments defined STLDI as coverage of less than 12 months to accommodate 12-month preexisting condition exclusion periods imposed by group health plans and group health insurance issuers when a new hire did not have 12 months of creditable coverage that ended no more than 63 days prior to the enrollment date in the plan or coverage.[133] Once preexisting condition exclusions were prohibited and the Departments implemented a limit on employee waiting periods of up to 90 days plus a 1-month reasonable and bona fide employment-based orientation period (as defined in section 9801(b)(4) of the Code, section 701(b)(4) of ERISA, and 2704(b)(4) of the PHS Act),[134] and comprehensive coverage in the individual market was guaranteed available to individuals through or outside of the Exchanges, the Departments determined that a shorter duration for STLDI was more appropriate and revised the definition in the 2016 final rules.[135] Subsequently, when the Departments were concerned about the availability of affordable health insurance options, the Departments lengthened the initial contract term to less than 12 months with a maximum allowed duration of 36 months (including renewals and extensions) in the 2018 final rules.[136] [137]

The definition of STLDI in the 2023 proposed rules, and that the Departments are finalizing in these final rules, is consistent with applicable Federal law (for example, the Code, ERISA, and the PHS Act). The 2023 proposed rules proposed a revised Federal definition that set standards for STLDI that clearly distinguish it from individual health insurance coverage that is subject to the Federal consumer protections and requirements. This proposal and the definition finalized in these rules is consistent with Congress maintaining the exclusion of STLDI from the PHS Act definition of individual health insurance coverage. Further, as noted by commenters and discussed in section III.A.2 of this preamble, the new definition gives reasonable meaning to the terms "short-term" and "limited-duration" since they reflect periods of time that are brief in comparison to the length of comprehensive coverage sold with an initial term of 12 months, on a guaranteed renewable basis.[138] The

[128] *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury*, 966 F.3d 782 (D.C. Cir. 2020), *aff'd* 966 F.3d 782 (D.C. Cir. 2020).

[129] *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury*, 966 F.3d 782 (D.C. Cir. 2020).

[130] *Id.* at 789.

[131] *Id.* at 789 and 792 (citing to *Encino Motorcars, LLC* v. *Navarro*, 136 S. Ct. 2117, 2125 (2016)).

[132] *See, for example*, 88 FR 44596 at 44610, 44612, 44614–44618 (July 12, 2023) (discussing how the proposed changes to definitions of "short-term" and "limited-duration" and the proposed modifications to the required consumer notice would allow consumers to better distinguish between STLDI and comprehensive coverage).

[133] 62 FR 16894 (April 8, 1997). *See also* 69 FR 78,720 (December 30, 2004) (finalizing the definition of STLDI in the 1997 HIPAA interim final rules).

[134] 26 CFR 54.9815–2708, 29 CFR 2590.715–2708, and 45 CFR 147.116.

[135] 81 FR 75316 at 75317, 75318 (October 31, 2016).

[136] As noted previously, the Departments' authority to issue the 2018 final rules was challenged and upheld in *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury*, 966 F.3d 782 (D.C. Cir. 2020). *See also Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury*, 392 F.Supp.3d 22 (D.D.C. 2019).

[137] 83 FR 38212 at 38218 (August 3, 2018).

[138] As the court noted in *Ass'n for Community Affiliated Plans* v. *U.S. Department of the Treasury*

Continued

definition of STLDI in the 2023 proposed rules and these final rules is consistent with the original intent of HIPAA, as reinforced by the ACA, to provide temporary, stopgap coverage for individuals transitioning between comprehensive coverage.

Some commenters suggested that the Departments failed to provide sufficient justification, or lacked sufficient data or analysis, to support the proposed changes to the Federal definition of STLDI, particularly with respect to the changes to limit the initial duration of STLDI policies to 3 months, and the maximum duration to 4 months including renewals and extensions. In addition, one commenter expressed concern that an abrupt change to the maximum duration of STLDI may have unintended consequences on overall health care coverage and consumer choices, as occurred when the Departments increased the maximum duration of STLDI from less than 3 months to less than 12 months in the 2018 final rules. Some commenters suggested that the 2023 proposed rules would impose a market-disrupting change in the duration of STLDI without providing evidence to support this change.

As the Supreme Court stated in *Encino Motorcars* v. *Navarro,*[139] and the D.C. Circuit Court repeated in *Association for Community Affiliated Plans* v. *U.S. Department of the Treasury,*[140] "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." The Departments satisfy this requirement; the proposed rules and these final rules provide a reasoned explanation of the changes to the Federal definition of STLDI. As explained in section III.A.2 of this preamble, the Departments determined that it is necessary and appropriate to amend the Federal definition of STLDI to ensure that consumers can clearly distinguish STLDI from individual health insurance coverage, protect the risk pools and stabilize premiums for individual health insurance coverage, and promote access to affordable comprehensive coverage. While the Departments acknowledge that they have limited data on enrollment in STLDI, the Departments have sufficient information and evidence to conclude that the changes to the definition finalized in these rules are appropriate and justified. The Departments are of the view that these final rules are necessary and appropriate to combat deceptive marketing practices, distinguish STLDI from individual health insurance coverage, and address the changes in the legal landscape and market conditions from 2018 to 2024. Further, as discussed in section II.A of this preamble, since the publication of the 2018 final rules, comprehensive coverage for individuals has generally become more accessible and affordable, and while affordability concerns persist among consumers, STLDI is an inadequate substitute for comprehensive coverage.

Aggressive, deceptive marketing practices are an ongoing challenge for consumers shopping for coverage. As discussed in section II.B and section III.A.3 of this preamble, recent secret shopper studies have detailed ongoing practices by sellers of STLDI that do not inform consumers of eligibility for less expensive Exchange plans or that provide misleading information about STLDI with limited benefits.[141] Deceptive marketing practices can have devastating financial implications for consumers that purchased STLDI without fully understanding its limitations and later encounter unexpected and expensive medical events that are not covered by their insurance.[142] In addition, as explained in section III.A.2 of this preamble and the preamble to the 2023 proposed rules, the Federal definition for STLDI in these final rules is consistent with the group market rules regarding the 90-day waiting period provision under the ACA and with STLDI's traditional role of serving as temporary coverage for individuals transitioning between other types of comprehensive coverage. The definition is also similar to the less-than-3-month maximum term for STLDI under the 2016 final rules and under a number of State laws and aligns with the goal of Executive Order 14009 to support protections for people with preexisting conditions. The Departments have weighed the potential benefits and costs to consumers when developing the proposed rules and these final rules and concluded the changes will not unduly harm consumers.[143]

While the Departments are of the view that the changes to the Federal definition of STLDI finalized in these rules are critical, these final rules take steps to limit the potential of the rules having an abrupt, disruptive effect, particularly with respect to consumers currently enrolled in STLDI coverage, and to address the potential reliance interests of both issuers offering STLDI and consumers enrolled in STLDI under the 2018 final rules. As discussed in section III.A.6 of this preamble, with the exception of the notice provision, these final rules will not be applicable to STLDI policies sold or issued before September 1, 2024. This will result in a phased-in approach that limits the potential for market disrupting impact by allowing individuals currently enrolled in STLDI to maintain coverage that meets the standards in the 2018 final rules through the duration of their current policy. In addition, this phased-in approach does not require issuers who have relied on the current rules to modify contracts for STLDI policies that are currently in place. Further, the proposed changes that are finalized in these rules will not result in an abrupt change in the maximum permitted duration of STLDI in many States. Of the States that currently permit STLDI, seven States and the District of Columbia already have a maximum permitted length of less than 3 months for STLDI while four additional States prohibit the sale of STLDI entirely, notwithstanding the longer duration permitted under the 2018 final rules.[144] Finally, as these final rules intend to protect against misleading marketing practices that harm consumers, the benefits of further differentiating STLDI from comprehensive coverage outweigh any potential unintended consequences of changing the maximum allowable duration of STLDI. As outlined in this section and elsewhere in these rules, the definition is well reasoned, is clearly

regarding the STLDI definition adopted in the 2018 final rules, "(u)nder the Departments' definition, 'short-term' refers to the initial contract term, while 'limited-duration' refers to the policy's total length, including renewals. This reasonable reading gives independent meaning to each term." 966 F.3d at 789. The Departments are applying the same general framework to establish the new definition adopted in these final rules, with "short-term" referring to the initial contract term and the term "limited-duration" referring to the policy's total length, including extensions and renewals.

[139] 136 S. Ct. 2117, 2125 (2016).

[140] 966 F. 3d at 792.

[141] Schwab, R., & Volk, J. (August 28, 2023). "The Perfect Storm: Misleading Marketing of Limited Benefit Products Continues as Millions Losing Medicaid Search for New Coverage," Center on Health Insurance Reforms, available at: *https://chirblog.org/the-perfect-storm-misleading-marketing-of-limited-benefit-products-continues-as-millions-losing-medicaid-search-for-new-coverage.*

[142] Deam, Jenny (2021). "He Bought Health Insurance for Emergencies. Then He Fell Into a $33,601 Trap," ProPublica, available at: *https://www.propublica.org/article/junk-insurance.*

[143] *See* the Regulatory Impact Analysis in section V of this preamble.

[144] *See Healthinsurance.org* (2023). "Duration and Renewals of 2023 Short-Term Medical Plans by State," available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf; see also* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-term Limited-duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

within the Departments' authority, and is consistent with other applicable Federal law, and is therefore not arbitrary and capricious.

Some commenters expressed concern that the proposed definition of STLDI would interfere with the authority of States to regulate insurance pursuant to the McCarran-Ferguson Act and PHS Act. These commenters stated that the McCarran-Ferguson Act reserves the regulation of insurance to States so that States can tailor their health insurance policies to the needs of their residents. They stated that State regulators are better positioned to understand the unique characteristics and requirements of each State's respective insurance markets and are more responsive to the needs of their insurance markets. Another commenter stated that under the PHS Act, Federal authority to regulate insurance is secondary to the primary authority of the States, and any Federal intrusion on State authority must be based on information that a State may not be substantially enforcing PHS Act requirements. A commenter noted that States have demonstrated their willingness and capacity to regulate STLDI coverage because half of States have regulations in place. For example, the commenter noted that the sale of STLDI is prohibited in some States [145] and other States have restricted the maximum allowed term of STLDI to 3, 6, or 12 months or coverage that terminates at the end of the calendar year.[146] Other commenters stated that some States only allow limited renewals of STLDI. Another State regulates STLDI by requiring that STLDI policies sold in the State provide certain consumer protections, implementing a separate risk pool, and creating a special enrollment period for consumers that exhaust the 36-month period of STLDI coverage, while setting minimum benefit and coverage requirements to meet the needs of seasonal employees that desire flexibility and low-cost health care coverage.[147] A commenter noted that 12 States currently prohibit health status underwriting for STLDI, which effectively bans STLDI in those States. The commenter stated that the proposed rules fail to balance States' interest in regulating health insurance issuers and their health insurance markets with Congress's intent to provide protections to consumers. On the other hand, a few commenters noted that variation in State oversight of STLDI has resulted in a patchwork of consumer protections across States, and one commenter stated that consumers would benefit from national-level STLDI regulation.

These final rules establish the Federal definition of STLDI with respect to the maximum length of the initial contract term, the maximum allowable duration (including renewals and extensions), and a consumer notice. The Departments acknowledge and respect States' authority to regulate the business of insurance. The Departments generally agree that States retain the authority to regulate STLDI and further note that these final rules do not change or otherwise modify the existing ERISA or PHS Act preemption standard.[148] As such, States may impose requirements tailored to the needs of their populations, and may adopt limitations on stacking, as well as limitations on sales and marketing practices. Relatedly, in section III. B of this preamble, in these final rules, the Departments added language to the notice to alert consumers as to how the coverage they are purchasing might vary from individual health insurance coverage. States may impose additional language requirements for a consumer notice and remain free to regulate STLDI.

The Departments agree that the States play an important role in regulating STLDI and recognize the federalism implications of the proposed rules and these final rules.[149] As noted by commenters, the McCarran-Ferguson Act generally affirms the preeminence of State regulation, and also explicitly allows for Federal regulation when an act of Congress specifically relates to the business of insurance.[150] However, the commenters' argument that Federal authority to regulate insurance is secondary to the primary authority of the States conflates Federal authority to regulate insurance under section 1012 of the McCarran-Ferguson Act with HHS's authority under section 2723 of the PHS Act to enforce requirements in part A and D of title XXVII of the PHS Act against issuers.[151] Under section 2723 of the PHS Act, States have authority to enforce the requirements of part A and D of title XXVII of the PHS Act, and where the State fails to substantially enforce a provision (or provisions) of part A or D with respect to health insurance issuers in the State, HHS shall enforce such provision (or provisions) in the State. In contrast, the McCarran-Ferguson Act balances State and Federal interests in regulating the business of insurance. Section 1012(a) of the McCarran-Ferguson Act maintained State regulatory authority by enabling State preemption of some Federal law, and section 1012(b) of the McCarran-Ferguson Act limited Federal regulatory authority by generally exempting the "business of insurance" from Federal law.[152] Although Congress allowed an exception for State preemption of Federal law in this way, Congress also preserved Federal authority to regulate insurance provided that, to overcome the State preemption, congressional action must specifically relate to the

[145] The commenter noted that STLDI is not for sale in a number of States including California, Colorado, Connecticut, Hawaii, Maine, Massachusetts, New Jersey, New Mexico, New York, Rhode Island, Vermont, and Washington. *See also Healthinsurance.org* (2023). "Duration and Renewals of 2023 Short-Term Medical Plans by State," available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf* (As of September 6, 2023, STLDI is not for sale in 14 States—California, Colorado, Connecticut, Hawaii, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New Mexico, New York, Rhode Island, Vermont, and Washington—and the District of Columbia.)

[146] The commenter stated that Illinois allows the sale of STLDI that lasts for up to 180 days, and in New Hampshire, STLDI contracts can last for up to 6 months with a renewal or extension of up to a total of 18 months.

[147] The commenter stated that Iowa imposed minimum benefit and coverage requirements on short-term plans above Federal standards.

[148] Section 731 of ERISA and sections 2724 and 2762 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a) and 148.210(b)).

[149] *See* 88 FR at 44648–44649. *See also* the federalism discussion in section V.H of this preamble.

[150] *Compare* "The business of insurance, and every person engaged therein, shall be subject to the laws of the several States which relate to the regulation or taxation of such business . . ." 15 U.S.C. 1012(a), *with* "No Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance, or which imposes a fee or tax upon such business, unless such Act specifically relates to the business of insurance: Provided, that after June 30, 1948, the Act of July 2, 1890, as amended, known as the Sherman Act, and the Act of October 15, 1914, as amended, known as the Clayton Act, and the Act of September 26, 1914, known as the Federal Trade Commission Act, as amended [15 U.S.C. 41 *et seq.*], shall be applicable to the business of insurance to the extent that such business is not regulated by State Law. . . ." 15 U.S.C. 1012(b).

[151] HHS also has authority under section 2761 of the PHS Act to enforce the requirements in part B of title XXVII of the PHS Act against issuers in situations where a State fails to substantially enforce one or more provisions of part B with respect to health insurance issuers in the State.

[152] *See* Steffen, Peter B. (2000) "After Fabe: Applying the *Pireno* Definition of Business of Insurance in First-Clause McCarran-Ferguson Act Cases," University of Chicago Legal Forum: Vol. 2000, available at: *https://chicagounbound.uchicago.edu/uclf/vol2000/iss1/15* ("The first clause enabled [S]tate law to supersede [F]ederal law; the second clause provided a [F]ederal antitrust exemption for the 'business of insurance' . . . The Act gave [S]tates some powers they did not have before, by stating in the first clause that only a [F]ederal law that 'specifically relates to the business of insurance' can preempt a [S]tate law dealing with insurance. Congressional legislation merely affecting insurance would not meet the first-clause test and thus would not, be exempt from the general prohibition on preemption. Rather, in order to apply, [F]ederal law must specifically relate to the 'business of insurance' . . .").

business of insurance.[153] It is without question that HIPAA, the ACA, and the other Acts of Congress that added Federal consumer protections and requirements applicable to health insurance issuers offering group and individual health insurance coverage specifically relate to the business of insurance. In addition, as discussed earlier, the Departments have clear legal authority to define STLDI and set standards to distinguish it from individual health insurance coverage. This includes authority to adjust the interpretations for and implementation of the terms "short-term" and "limited-duration" that set the length of the initial contract term and the maximum duration (including renewals and extensions) for STLDI, as well as to update the consumer notice. As outlined previously, Congress provided the Departments with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act. The Departments are of the view that the Federal regulatory definition of STLDI in these final rules is necessary and appropriate to carry out the provisions of the Code, ERISA, and the PHS Act. Further, the Departments must give meaning to the undefined statutory term STLDI, and the meaning must distinguish it from individual health insurance coverage. This is because the PHS Act imposes certain requirements on individual health insurance coverage and does not impose those same requirements on STLDI. The Departments are also of the view that it is necessary and appropriate for consumers considering the purchase of STLDI, and those purchasing such insurance, to be aware that such coverage is not subject to the Federal consumer protections and requirements for comprehensive coverage. Defining STLDI in a way that requires a short, standard description of how the coverage might vary from individual health insurance coverage allows for a clear determination by regulators that the policy is STLDI, and promotes ease of understanding by consumers. As explained previously and detailed in the 2023 proposed rules, the changes to the Federal definition of STLDI, including the updates to the consumer disclosure notice, are reflective and responsive to changes observed by the Departments in market conditions and the legal landscape.

These final rules define STLDI for purposes of the Code, ERISA, and the PHS Act. Insurance coverage that meets the definition of STLDI in these final rules will qualify for the exception to the Federal definition of individual health insurance coverage and be exempt from the Federal consumer protections and requirements applicable to comprehensive coverage. Nothing in these final rules prevents regulation of STLDI for purposes of State law. For example, States may determine whether to permit the sale of STLDI in their insurance markets. If a State law permits or requires an action that is inconsistent with the Federal definition of STLDI, any coverage offered pursuant to that State law that does not meet the standards set forth in these final rules would not qualify as STLDI under these final rules and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. For example, if a State were to prohibit policies issued in that State from including the Federal consumer notice, then coverage in that State that did not include the Federal consumer notice language would not qualify for the exclusion from the PHS Act definition of individual health insurance coverage and thus would be subject to the Federal consumer protections and requirements applicable to individual health insurance coverage.

Amending the Federal regulation defining STLDI protects the distinctively Federal role and interest in ensuring that the Federal definition for STLDI clearly distinguishes STLDI from individual health insurance coverage for consumers in every State. As discussed in the preamble to the 2023 proposed rules, many STLDI policies that are sold through associations are sold across numerous States. Often consumers are purchasing STLDI policies in a different State from the State in which the policy is regulated. This can create challenges for both consumers and State regulators. The Departments are of the view that establishing a shorter Federal maximum duration for STLDI may reduce the incentives for issuers to offer STLDI through associations to the extent that they are using associations as a way to avoid State limits on duration. This, in turn, will help minimize consumer confusion related to coverage offered through associations. In addition, STLDI with a shorter maximum allowable duration would decrease the impact of STLDI on Federal Government spending. As discussed in section III.A.6 of this preamble, STLDI that has a maximum allowable duration of up to 36 months, including renewals and extensions, has an annual impact on Federal PTC spending due to selection-induced effects.

The Departments are of the view that these final rules appropriately balance States' interests in regulating health insurance issuers and their health insurance markets with Congress' intent to establish a general Federal framework for health insurance coverage, including the provision of certain key protections to consumers enrolled in comprehensive coverage.

Some commenters expressed general support for the proposed definition of STLDI. Commenters in favor of the proposed definition noted that it would return STLDI to its traditional and intended purpose of providing temporary, stopgap coverage between periods of comprehensive coverage, and not serve as a long-term substitute for comprehensive coverage. Some of these commenters highlighted that low health literacy rates, a long maximum allowed term of STLDI that mimics the duration of comprehensive coverage, and deceptive marketing practices cause many consumers to confuse STLDI with comprehensive coverage. These commenters also stated that STLDI lacks Federal consumer protections and is inadequate to serve patients grappling with complex medical needs such as those that require maternity care or habilitative care; behavioral health problems; or chronic diseases such as cancer and cardiovascular disease. These commenters further stated that unwary consumers unexpectedly are underinsured when they enroll in STLDI and may end up forgoing needed, routine medical treatment and exacerbating chronic medical conditions because of limited benefits or high cost-sharing responsibilities. Consequently, consumers may then be sicker when they finally seek care in the emergency room for untreated medical conditions, which can increase costs absorbed by providers and facilities, costing the health care system more in the long run. Commenters who supported the STLDI definition in the proposed rules warned that some consumers who enroll in STLDI as an alternative to comprehensive coverage can become subject to unexpected medical debt leading to unforeseen long-term financial consequences. Other commenters that supported the revised Federal definition for STLDI stated that while STLDI is highly profitable for health insurance issuers, agents, and brokers, the impact of STLDI on the risk pools for individual health insurance coverage indicates that it is necessary to clarify the distinctions between STLDI

[153] *Id.*, citing Lee R. Russ, 3 Couch on Insurance sec. 2:4 at 2–12 (Clark 1994) ("McCarran-Ferguson turns the traditional rule of [F]ederal preemption of [S]tate law on its head.").

and comprehensive coverage. Other commenters expressed general opposition to the STLDI definition proposed in the 2023 proposed rules. These commenters stated that while STLDI is not adequate coverage for everyone, STLDI provides a useful, short-term, affordable option, particularly for consumers who do not have access to PTC subsidies, and provides access to specialists that are not in-network with many comprehensive coverage options.

The Departments acknowledge that the changes to the Federal definition of STLDI that are finalized in these rules may result in individuals who prefer STLDI losing access to such coverage as a long-term coverage option. However, as explained previously and in the 2023 proposed rules, the Departments have concluded that these concerns are now outweighed by the negative financial and health consequences that some individuals who enroll in STLDI in lieu of comprehensive coverage experience; consumer challenges in differentiating STLDI from individual health insurance coverage, particularly in light of low health literacy rates and aggressive marketing; and the negative impact on the risk pools for individual health insurance coverage when healthier individuals enroll in STLDI in lieu of individual health insurance coverage.[154]

As the availability of affordable comprehensive coverage options has increased since the 2018 final rules were finalized, the Departments are of the view that STLDI is no longer needed to provide a year-round coverage option for individuals and should be limited to a temporary coverage option for shorter periods when an individual experiences gaps between comprehensive coverage. The Departments agree with commenters that the definition of STLDI under the 2018 final rules heightened the risk that uninformed consumers will mistakenly purchase STLDI as a substitute for comprehensive coverage, and under current market conditions, unnecessarily expose themselves to severe financial risks if they have complex medical needs or conditions. The Departments agree with commenters that the lack of key Federal consumer protections and requirements that apply to benefits offered by STLDI[155] results in STLDI being an inadequate substitute for comprehensive coverage, especially for those with complex medical needs. Some consumers with complex health conditions may enroll in STLDI because a preferred provider may be in-network with an STLDI policy but out-of-network with comprehensive coverage plans.[156] However, STLDI plans are typically associated with higher overall financial risk due to high premium increases that may be imposed upon an individual whose health condition worsens. For example, a study that examined the potential impacts of STLDI and associated State policies on cancer diagnoses found that individuals in States that prohibited STLDI were associated with an increase in early-stage cancer diagnoses when compared to States that did not regulate STLDI.[157] In addition, because issuers of STLDI can engage in medical underwriting, individuals can be charged higher premiums based on health status, gender, age and other factors.[158] Enrolling in comprehensive coverage instead of STLDI prior to when a consumer is diagnosed with a complex medical condition or incurs major medical expenses will promote access to care and improve overall health outcomes.

In addition, the Departments share commenters' concerns that low health literacy rates can have a detrimental impact on health insurance decision-making, putting some consumers at increased risk for purchasing STLDI when they are looking to purchase comprehensive coverage. Low health literacy rates combined with potentially erroneous assumptions about minimum standards for coverage makes the average consumer vulnerable to deceptive marketing practices and creates barriers to accessing health care and comprehensive coverage. As discussed in the preamble to the 2023 proposed rules, consumers may not understand that while some STLDI policies may have lower premiums than comprehensive coverage, consumers may incur steep and potentially debt-inducing health care bills once enrolled in STLDI due to limited benefits provided by such coverage, limited Federal consumer protections, and high-cost sharing requirements.[159] A qualitative study cited by commenters examined consumer comprehension of marketing materials for STLDI and found that not only did participants have low health insurance literacy rates, but they struggled to understand the plan's limitations because the ACA has shaped their expectations about what "typical" health plans cover.[160] As a result, consumers often expect that all health insurance provides the same benefits and protections even absent deceptive marketing practices, increasing the importance of guardrails to distinguish comprehensive coverage from STLDI. These concerns are exacerbated in underserved communities, given their low rates of health literacy.[161] As discussed in the 2023 proposed rule, in addition to systemic and social structures that impact access to health care,[162] health literacy can make it more difficult for historically underserved and marginalized groups to navigate high deductibles, expanded cost sharing, coverage exclusions and narrow formularies found in STLDI.[163] These barriers can lead to consumers rationing their medicine or not taking it at all or delaying necessary health care services, causing devastating consequences to

[154] *See* section V of this preamble for the regulatory impact analysis; *see also* 88 FR 44596 at 44608 (2023).

[155] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[156] In some circumstances, even accounting for the expense of using an out-of-network provider, comprehensive coverage still may be the less expensive choice overall because of lower out-of-pocket spending a consumer would enjoy when enrolled in comprehensive coverage. In many cases, expenses for premiums and cost sharing for comprehensive coverage enrollees are still lower than the uncovered costs associated with STLDI, particularly when an individual undergoes costly medical treatment.

[157] Barnes, Justin, Anne Kirchhoff, Robin Yabroff, and Fumiko Chino (2023). "State Policies Regulating Short-Term Limited Duration Insurance Plans and Cancer Stage at Diagnosis," *JNCI Cancer Spectrum*, Volume 7, Issue 5, available at: *https://doi.org/10.1093/jncics/pkad060.*

[158] *See* Pollitz, Karen, Michelle Long, Ashley Semanskee, and Rabah Kamal (2018). "Understanding Short-Term Limited Duration Health Insurance," KFF, available at: *https://www.kff.org/affordable-care-act/issue-brief/understanding-short-term-limited-duration-health-insurance. See also* Lueck, Sarah (2018). "Key Flaws of Short-Term Health Plans Pose Risks to Consumers," Center on Budget and Policy Priorities, available at: *https://www.cbpp.org/research/health/key-flaws-of-short-term-health-plans-pose-risks-to-consumers.*

[159] *See, for example,* 88 FR 44596 at 44608, 44612, 44613, 44615–44617, 44646 (July 12, 2023).

[160] Georgians for a Healthy Future (2019). "Report on Testing Consumer Understanding of a Short-Term Health Insurance Plan," available at: *https://healthyfuturega.org/wp-content/uploads/2019/04/Consumer-Testing-Report_NAIC-Consumer-Reps.pdf.*

[161] Kutner M, Greenberg E, Jin Y, Paulsen C. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006–483). Washington, DC: U.S. Department of Education, National Center for Education Statistics; 2006.

[162] Muvuka, B., *et al* (2020). "Health Literacy in African-American Communities: Barriers and Strategies," *Health Literacy Research and Practice*, available at: *https://journals.healio.com/doi/full/10.3928/24748307-20200617-01.*

[163] 88 FR 44596 at 44608, 44613, 44615 (July 12, 2023).

their health.[164] Shortening the maximum allowable term and duration of STLDI will serve as a clear indicator to consumers about the nature of each coverage option and instill more confidence in their coverage decisions. The Departments are also concerned about the prevalence of deceptive marketing practices, as noted by commenters who referenced secret shopper studies and anecdotes about negative consumer experiences, including when deceptive marketing practices were used to encourage consumers to enroll in STLDI instead of receiving education about their eligibility for low-cost comprehensive coverage or to inhibit consumers from choosing the coverage they need to access health care and protect themselves from financial burdens.

Finally, the Departments agree that it is necessary and appropriate to revisit the Federal STLDI definition to further distinguish between these types of coverage given concerns about the impact on risk pools. As discussed in section II.C of this preamble, STLDI siphons off healthier individuals from the risk pools for individual health insurance coverage, thereby raising premiums for such coverage.

Some commenters expressed particular concern about the impact of deceptive and aggressive marketing practices for STLDI given the increase in consumers currently looking for health coverage options as States resume Medicaid eligibility redeterminations due to the expiration of the FFCRA Medicaid continuous enrollment condition, as discussed in section II.B of this preamble. These commenters explained that many consumers who lose Medicaid coverage and are seeking new coverage at a low cost will be vulnerable to misleading or aggressive sales and marketing tactics that obscure the differences between comprehensive coverage and STLDI, and might therefore mistakenly enroll in STLDI in lieu of comprehensive coverage. These commenters noted that underserved populations with low health literacy and incomes below the FPL may be particularly vulnerable.

The Departments recognize that more individuals may be considering new coverage options as a result of an increased volume of Medicaid eligibility redeterminations, and therefore may be particularly susceptible to this type of misleading or aggressive sales and marketing tactics even though affordable options for comprehensive coverage may be available to them. CMS has made it a priority to ensure that as many people as possible maintain continuous comprehensive coverage during this "unwinding period."[165] CMS has a robust plan in place to reach people with Medicaid or CHIP coverage, so that they are aware of the steps they need to take to maintain their Medicaid or CHIP coverage, or, if no longer eligible, to smoothly transition to other forms of coverage, such as individual health insurance coverage purchased through an Exchange.[166] This plan includes new policy and operational flexibilities, such as a temporary exceptional circumstances special enrollment period available through *HealthCare.gov* for qualified individuals and their families who lose Medicaid or CHIP coverage following the end of the continuous enrollment condition; multi-pronged, large-scale national and local outreach and stakeholder engagement efforts; and investments and innovations in enrollment assistance.[167] State-based Exchanges have taken similar steps to update or implement new special enrollment period policies, as well as conduct outreach and stakeholder engagement, to support qualified individuals and their families who lose Medicaid or CHIP coverage following the end of the continuous enrollment condition. Despite these efforts, current data shows that a substantial number of people have lost coverage and may want to enroll in coverage.[168]

Commenters requested that the Departments clarify whether any of the existing special enrollment periods would allow a consumer to access comprehensive coverage if their STLDI coverage ends outside of an open enrollment period. Some commenters recommended that the Departments create a new special enrollment period for individuals to enroll in comprehensive coverage after their STLDI coverage ends, or that allows an individual to enroll in coverage through an Exchange upon the termination of STLDI coverage specifically for situations where a consumer elected STLDI following a loss of employment-based coverage due to a job transition or to provide temporary coverage during an employer's waiting period. Some commenters expressed concern about the potential for consumers to experience gaps in coverage in the absence of access to a special enrollment period, explaining that those consumers purchasing a 3-month STLDI plan mid-calendar year would become financially vulnerable with no continued coverage options until the next open enrollment period.

The Departments affirm that individuals who lose eligibility for STLDI coverage, such as when their STLDI policy ends, are already eligible for a special enrollment period and have 60 days to enroll in group health plan coverage, either insured or self-funded.[169] HHS did not propose to create a new individual market special enrollment period for individuals to enroll in individual health insurance coverage (on- or off-Exchange) at the expiration of their STLDI coverage and declines to do so in these final rules. Providing consumers with an individual market special enrollment period to purchase off-Exchange or on-Exchange coverage when they lose eligibility for STLDI or their STLDI policy ends could confuse or mislead consumers who are considering their health coverage options. Consumers may delay enrolling in comprehensive coverage when first available, on the expectation that such coverage would be available at any time, even if STLDI coverage does not renew or is otherwise terminated. Also, as explained previously, inflating the fraction of low-risk individuals who enroll in STLDI rather than individual health insurance coverage will have negative consequences for the risk pools for individual health insurance coverage.

Furthermore, there are other options for individuals who anticipate experiencing longer gaps between comprehensive coverage. For example, an individual who loses comprehensive

[164] Schumacher, Jessica R. *et al.* (2013). "Potentially Preventable Use of Emergency Services: The Role of Low Health Literacy," *Medical Care* 51(8), August 2013, available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3756810.*

[165] *See* Temporary Special Enrollment Period (SEP) for Consumers Losing Medicaid or the Children's Health Insurance Program (CHIP) Coverage Due to Unwinding of the Medicaid Continuous Enrollment Condition—Frequently Asked Questions (FAQ) (January 27, 2023), available at: *https://www.cms.gov/technical-assistance-resources/temp-sep-unwinding-faq.pdf.*

[166] *See* CMS (2023). "Unwinding and Returning to Regular Operations after COVID, Medicaid and CHIP Renewals Outreach and Educational Resources," available at: *https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/medicaid-and-chip-renewals-outreach-and-educational-resources/index.html.*

[167] *See* CMS (August 26, 2022). "Biden-Harris Administration Makes Largest Investment Ever in Navigators Ahead of *HealthCare.gov* Open Enrollment Period," available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-makes-largest-investment-ever-navigators-ahead-healthcaregov-open.*

[168] *See* Corallo, Bradley, Jennifer Tolbert, Patrick Drake, Sophia Moreno, and Robin Rudowitz, (2024). "Halfway Through the Medicaid Unwinding: What Do the Data Show?" KFF, available at: *https://www.kff.org/policy-watch/halfway-through-the-medicaid-unwinding-what-do-the-data-show.*

[169] *See* 26 CFR 54.9801–6, 29 CFR 2590.701–6, 45 CFR 146.117.

coverage may be eligible for a special enrollment period that allows them to enroll in group coverage sponsored by their employer, the employer of their parent, spouse or partner, or individual health insurance coverage, either directly with the issuer, or through the Exchanges, where they may be eligible for APTC.[170] [171] In some circumstances, they may be eligible for other coverage such as government-based assistance for qualified individuals under Medicaid, CHIP, or BHP.[172] In addition, if a consumer experiences a reduction in benefits or termination of employment and is uncertain as to when they will be eligible for other comprehensive coverage, the consumer in many cases has the option of electing coverage under the Consolidated Omnibus Budget Reconciliation Act (COBRA) [173] (18, 29, or 36 months depending on the nature of the COBRA qualifying event) or State mini-COBRA continuation coverage laws. Also, as discussed in section III.A.2 of this preamble, an individual who enrolls in STLDI coverage from one issuer and wishes to purchase another STLDI policy maintains the option of enrolling in STLDI coverage with another issuer that is not a member of the same controlled group.

One commenter suggested that the Departments require that certain consumer protection provisions apply to STLDI. Other commenters urged the Departments to extend the prohibition on rescissions to STLDI. One of these commenters explained that STLDI issuers can rescind the patient's coverage following post-claims underwriting,[174] leaving patients without any financial or medical protection and at high risk of incurring medical debt.

The Departments appreciate commenters' suggestions regarding ways in which to ensure STLDI provides key Federal consumer protections. The Departments agree that STLDI can place a consumer's health and financial well-being at risk if they experience a significant medical event or have a complex medical condition. As discussed in this preamble at section II.B, consumers may be susceptible to deceptive marketing and sales practices that often mask post-claims underwriting practices by STLDI issuers and the exclusion of key essential health benefits and Federal consumer protections under STLDI plans. Consumers may be unaware of the limitations of their STLDI coverage until they need care or have incurred significant medical expenses, particularly those with low health literacy. However, the Departments did not propose to apply Federal consumer protections to STLDI and are not finalizing in these final rules the extension of any of the individual health insurance coverage Federal consumer protections and requirements to STLDI.[175] The Departments further note it would be inconsistent with the statute to extend the Federal prohibition on rescissions to STLDI, as Congress limited its applicability to group health plans and health insurance issuers offering group or individual health insurance coverage.[176] In addition, as discussed in section III.A.2 of this preamble, the Departments have determined that limiting extensions and renewals of STLDI instead of applying guaranteed renewability to STLDI appropriately distinguishes STLDI from individual health insurance coverage.

Other commenters suggested that the Departments collect data on key elements, including, for example, compensation paid by issuers to brokers or agents; plan-level enrollment/disenrollment and claims data that is disaggregated by age, income, race/ethnicity, and geographic locations; coverage limits; and other data to enable regulators and stakeholders to assess whether and how children and families are being served by STLDI.

The Departments agree with commenters that it would be useful to have access to more data on STLDI. HHS is committed to collecting information from issuers offering STLDI regarding any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in STLDI, as authorized under section 2746 of the PHS Act.[177] However, beyond this requirement, the Departments do not currently have authority to collect data from issuers of STLDI. States, in contrast, can survey and collect data on STLDI under State authority and the NAIC Market Analysis and Procedures Working Group annually collects data from issuers of STLDI.[178] The Departments encourage States that do not already collect such data to consider the collection of data from STLDI issuers, as suggested by commenters, to assist with Federal and State oversight of STLDI.

2. Definitions of "Short-term" and "Limited-duration"

The 2023 proposed rules proposed to amend the Federal definition of "short-term, limited-duration insurance" in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103 to reflect a new interpretation of the phrase "short-term" to mean a policy, certificate, or contract of insurance with an issuer that has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance.[179] The 2023 proposed rules also proposed to interpret "limited-duration" to mean a maximum coverage period that is no longer than 4 months in total, including renewals and extensions.[180] For this purpose, the Departments proposed that a renewal or extension would include the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer to the same policyholder within the 12-month period, beginning on the original effective date of the initial policy, certificate, or contract of insurance. As proposed, in this context, the phrase "same issuer" would refer to the entity licensed to sell the policy, consistent with the definition of health insurance issuer in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103. Under this proposal, the duration of coverage would be calculated based on the total number of days of coverage (either consecutive or non-consecutive) that a policyholder is enrolled in an STLDI policy with the same issuer within the prior 12-month period, regardless of whether the

[170] 45 CFR 155.420.

[171] 45 CFR 147.104(b)(2).

[172] Medicaid eligibility requirements vary by State.

[173] Public Law 99–272, April 7, 1986.

[174] Post-claims underwriting refers to the practice of engaging in an underwriting review after a claim is made rather than going through the time and expense of doing such a review to assess the consumer's actuarial risk and medical conditions at the time the policy is purchased.

[175] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI. Those requirements will be addressed by HHS in a separate rulemaking. *See* Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement; Proposed Rules, 86 FR 51730 at 51740–51744 and 51770–51771 (Sept. 16, 2021).

[176] *See* PHS Act section 2712.

[177] *See* Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement; Proposed Rules, 86 FR 51730 at 51740–51744 and 51770–51771 (Sept. 16, 2021).

[178] The NAIC is currently collecting additional data on STLDI as part of its Market Conduct Annual Statement data call for STLDI offered in 2023. *See https://content.naic.org/mcas-2023.htm.*

[179] 88 FR 44596 at 44610–44611 (July 12, 2023).

[180] *Id.* at 44611–44614 (July 12, 2023).

coverage issued to the policyholder is under the same or a new policy, certificate, or contract of insurance.

The calculation for the duration of coverage, however, would not include days of coverage under an STLDI policy, certificate, or contract of insurance sold to the same policyholder by a *different* issuer. As the Departments explained in the preamble to the 2023 proposed rules, this proposed distinction would effectively limit stacking of policies sold by the same issuer, would be easier for issuers to track and comply with than if applied across different issuers, and would allow consumers to purchase subsequent STLDI policies from other issuers within a 12-month period.[181]

As explained in the preamble to the 2023 proposed rules, the new proposed definition for STLDI is consistent with the group market rules regarding the 90-day waiting period provision under the ACA and with STLDI's traditional role of serving as a temporary coverage for individuals transitioning between other types of comprehensive coverage. The proposed definition is also similar to the less-than-3-month maximum term for STLDI under the 2016 final rules and under a number of State laws,[182] and aligns with the goal of Executive Order 14009 to support protections for people with preexisting conditions.

The Departments requested comments on the proposed new interpretations of the phrases "short-term" and "limited-duration." The Departments also requested comments on whether the interpretation of "short-term" in the proposed definition of STLDI should be some other length, such as no longer than 4 months, and why, and whether there are circumstances under which issuers should be allowed to renew or extend STLDI for periods of time beyond what would be permitted in the proposed rules. The Departments also requested comments on whether there are additional ways to differentiate STLDI from comprehensive coverage options, including information on State approaches or limits on the sale of STLDI by a different issuer, and how the subsequent issuer would determine whether or not an applicant had previous STLDI with another issuer. The Departments also solicited comments on whether to broaden the limits on stacking to include issuers that are members of the same controlled group.

Given that the majority of comments addressed the definitions of "short-term" and "limited-duration" together, the Departments are addressing comments related to the maximum allowed length and the definitions for these two terms together, along with the comments related to the practice of stringing together multiple or consecutive policies, a practice known as "stacking."

Commenters suggested various options for the allowable maximum duration. Some commenters supported finalizing the maximum duration as proposed. These commenters agreed that STLDI serves as an adequate gap filler for consumers that need a bridge between comprehensive forms of coverage, and a 3-month initial term makes it easier for a consumer to distinguish between STLDI and comprehensive coverage. In addition, some of these commenters supported a short initial term to protect consumers from the inherent risks of enrolling in coverage that does not provide Federal consumer protections or comprehensive health benefits, and to curb negative impacts on the risk pools for individual health insurance coverage. Some commenters were of the view that the proposed definitions of the terms "short-term" and "limited-duration" better align with the plain language of the statute than the current definitions. Others supported shortening the initial maximum allowable period to a period less than allowed under the current rules, but longer than the proposed 3-month period, for example a period of less than 6 months, to strike a balance between the drawbacks of STLDI with consumers' need for gap-coverage when coverage is needed for a short period of time, they have no other insurance options, or comprehensive coverage is otherwise unaffordable. Other commenters stated that STLDI policies should be permitted to have longer durations as long as they end by December 31 of the calendar year in which the policy period commences, at which point individuals can enroll in comprehensive coverage during the annual individual market open enrollment period. One commenter, who supported the proposed maximum duration, suggested that the Departments require that all initial contract terms end by December 31 of the policy year in which the policy commences (even when the STLDI policy is purchased late in the year), to minimize situations where consumers miss the annual individual market open enrollment period. The commenter suggested that requiring STLDI policies to end by December 31 would cause consumers to look for new coverage during the individual market open enrollment period and increase the likelihood that they would enroll in comprehensive coverage. The commenter further suggested that, for alignment with the proposed maximum duration, the Departments could allow renewal for up to 4 months (past December 31), but only if the full 4-month period of coverage is not sold at the same time and that an additional notice is sent to consumers about the annual individual market open enrollment period.

Other commenters opposed modifying the initial maximum allowed length of "short-term" and instead recommended keeping the 2018 final rule's maximum allowed length for an initial contract term of less than 12 months. With respect to the definition of "limited-duration," some commenters suggested the Departments redefine the standard to allow a longer maximum length than proposed. One commenter requested that the Departments define "limited-duration" as up to 12 to 18 months. Another commenter suggested that the Departments define "limited-duration" as up to 9 months in a 12-month period to allow consumers who do not have a qualifying event for a special enrollment period to purchase comprehensive coverage to use STLDI to bridge the gap between annual open enrollment periods in the individual market.

Commenters who supported a longer allowable maximum duration than the proposed period stated that limiting the maximum allowed length to no more than 3 months and a 1-month extension fails to account for all circumstances for which a consumer may need access to STLDI. Commenters gave examples of consumers who may benefit from being able to purchase longer-duration STLDI coverage, such as workers experiencing a change in employment, or unemployment; contract workers who do not have coverage through their employer; self-employed individuals or owners of a small business; college students who are not on their parent's insurance; workers in industries that require frequent travel, such as nurses and truckers; consumers with varying and unpredictable incomes; or consumers eligible for little or no APTC who would encounter a substantial premium expense if they enrolled in comprehensive coverage. In advocating for a longer maximum allowed duration, one commenter also noted that the average length of unemployment is 20.6 weeks, while according to a group of

[181] *Id.* at 44612 (July 12, 2023).

[182] *See, for example,* D.C. Code § 31–3303.13d; 18 Del. Admin. Code 1320–4.0; Haw. Rev. Stat. § 431:10A–605; Md. Code Ann., Insurance § 15–1301(s); N.M. Stat. § 13.10.3.8; Or. Rev. Stat. § 743B.005; and Ver. Stat. Ann. tit. 8 § 4084a(c). *See also Healthinsurance.org* (2023). "Duration and Renewals of 2023 Short-Term Medical Plans by State," available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf.*

issuers and marketers of STLDI the average length of enrollment in STLDI is only 7 months. Other commenters stated that the maximum allowable length of STLDI should be left to the States. Some commenters suggested the Departments require issuers offering STLDI with renewals and extensions of up to 4 months to guarantee that the renewal or extension be available to the consumer without additional underwriting if the consumer chooses to renew or extend their coverage.

Although the Departments acknowledge that there will be times when consumers may experience gaps in comprehensive coverage that exceed the maximum allowable duration for STLDI finalized in these rules, the Departments are not persuaded that a longer maximum initial contract term or longer maximum duration, taking into account renewals or extensions, is appropriate. Maintaining the definition that permits a longer initial length of up to 1 year would not alleviate the challenges consumers currently face in distinguishing STLDI from individual health insurance coverage, would continue to place consumers who enroll in STLDI at financial risk, and would not mitigate the impact on the risk pools for individual health insurance coverage or those consumers purchasing individual health insurance coverage. Because of low health literacy, consumers face the risk of inadvertently enrolling in STLDI coverage that does not sufficiently provide coverage for unexpected or significant medical events that arise during the coverage period.

The Departments are not persuaded by comments that urged the Departments to align the maximum duration with a time frame that reflects average periods of unemployment, such as 6 to 9 months, rather than the proposed limit. The limit of no-more-than 3 months with a 1-month extension aligns with the 90-day waiting period limitation and 1-month additional reasonable and bona fide employment-based orientation period that is permitted under the ACA. The Departments are of the view that aligning the maximum duration of an STLDI policy with the period Federal law expressly permits as an "orientation" period in employment-based coverage most appropriately reflects STLDI's traditional role to fill temporary gaps in coverage. Consumers who purchase STLDI during a 90-day waiting period have a predictable end to their gap in coverage. Their gap is defined, and generally temporary, and thus is exactly the type of gap that STLDI traditionally serves to fill. In contrast, a loss in coverage due to a loss of employment is not the type of gap that STLDI traditionally is intended to fill because consumers that experience a loss of employment do not have certainty regarding how long their gap in comprehensive coverage will be, and for some that gap will not be temporary and may extend beyond the average length of unemployment. By enrolling in STLDI in lieu of COBRA continuation coverage or individual health insurance coverage during the 60-day period for which they are eligible for a special enrollment period for loss of qualifying coverage, these consumers may lose access to comprehensive coverage until the next individual market open enrollment period. While STLDI may be an appropriate choice for some individuals during a period of unemployment, the Departments concluded that aligning the maximum duration with the 90-day waiting period limitation and 1-month additional reasonable and bona fide employment-based orientation period better captures the traditional role of STLDI. In addition, consumers are more likely to face an unexpected health issue during a longer coverage period—such as 6, 9, or 12 months—and may find themselves insufficiently protected by the typically limited benefits of an STLDI policy and potential resulting financial burdens.

By allowing an initial term of no more than 3 months, the interpretation of "short-term" for purposes of the revised Federal definition of STLDI finalized in these rules provides a clear demarcation from the 1-year length of a policy year for individual health insurance coverage. In addition, as discussed earlier, STLDI's traditional role is to provide coverage for temporary gaps for consumers transitioning between comprehensive coverage. A maximum period of no more than 3 months and 1-month extension (for a total maximum duration of 4 months, including renewals or extensions) is more appropriate for coverage intended to fill a temporary gap in comprehensive coverage. As explained in the preamble to the 2016 final rules, for longer gaps in coverage, guaranteed availability of coverage and special enrollment period requirements in the individual market under the ACA ensure that individuals can purchase individual health insurance coverage through or outside of the Exchange that is minimum essential coverage and includes the Federal consumer protections and requirements for comprehensive coverage.[183] Many consumers will also have the opportunity to enroll in comprehensive coverage offered by an employer and some may be eligible for other coverage, such Medicaid, CHIP or BHP.

The Departments are similarly not persuaded by the recommendation that STLDI be permitted to have a longer maximum duration, provided that coverage ends by December 31. Although the Departments appreciate that this approach would minimize gaps in coverage between when an individual's STLDI ends and when they can enroll in comprehensive individual health insurance coverage during the annual individual market open enrollment period, the Departments are concerned that such an approach would not sufficiently distinguish STLDI from individual health insurance coverage, which also ends on December 31. Finally, as mentioned in the 2023 proposed rules, the maximum allowable length of no more than 3 months and a 1-month extension represents a balance between providing a flexible standard that captures many of the circumstances for which an individual would want to enroll in STLDI, responds to the significant changes in the legal landscape and market conditions since the Departments last addressed STLDI, and addresses the low value that STLDI provides to consumers when used as a substitute for comprehensive coverage.

Some commenters requested that the Departments impose a guaranteed renewability requirement on STLDI to prevent additional underwriting if a consumer chooses to renew or extend their coverage. The Departments have determined that limiting extensions and renewals of STLDI instead of applying guaranteed renewability to STLDI appropriately distinguishes STLDI from individual health insurance coverage. As such, these final rules do not impose a guaranteed renewability requirement on STLDI. Underwriting practices, including post-claims underwriting are outside the scope of these final rules.

Many commenters supported the new proposed interpretation of "limited-duration" and accompanying proposed definition of renewal or extension to address stacking of STLDI policies by the same issuer to the same policyholder within a 12-month period. These commenters stated that issuers have exploited this loophole to sell consumers consecutive STLDI policies that collectively sidestep the maximum duration limits, deliberately misleading consumers about differences between STLDI and comprehensive coverage. According to some of these commenters, addressing the stacking loophole would reduce the risk of consumers unknowingly enrolling in coverage with

[183] 81 FR 75318 (Oct. 31, 2016).

inadequate benefits for an extended period of time. Commenters further stated stacking practices provide consumers with a false sense of security that they purchased a viable long-term substitute for comprehensive coverage and make it more challenging for consumers to distinguish STLDI from individual health insurance coverage. Commenters expressed concern about the exposure to financial risk that consumers face when purchasing stacked STLDI policies, explaining that a consumer typically faces new deductibles, new annual out-of-pocket limitations, and new preexisting condition limitations with each new STLDI policy term. A commenter noted that consumers may not understand that a health event experienced when covered under one STLDI policy could serve as the basis to impose a preexisting exclusion under a subsequent STLDI policy to deny benefits for the same condition.

Other commenters questioned the basis for the Departments to adopt this part of the definition of "limited-duration" to address stacking of policies sold by the same issuer, members of the same controlled group, and/or by unrelated issuers, stating that the Departments do not have authority to constrain consumer choice. A commenter argued that preventing consumers from purchasing subsequent STLDI policies from an issuer of their choice is contrary to the statute, which looks at the issuer's conduct rather than the consumer's conduct, and would run afoul of the decision in *Central United Life Ins. Co.* v. *Burwell*.[184] The commenter further stated that Congress unambiguously specified in the ACA and HIPAA the types of insurance and actors Congress intended to regulate, and Congress consistently chose to exempt STLDI from the definition of individual health insurance coverage and to regulate issuer behavior instead of consumer behavior. Another commenter encouraged the Departments to defer to States on whether and to what extent an issuer could sell consecutive or multiple STLDI policies to consumers within a 12-month period. Other commenters stated that addressing the stacking loophole would leave consumers financially vulnerable, as some will not understand that their STLDI coverage cannot be renewed or extended with the same issuer and will have limited coverage options outside the annual individual market open enrollment period.[185]

Some commenters who supported addressing the stacking loophole encouraged the Departments to extend the new interpretation of "limited-duration" and the accompanying definition of renewal or extension to include all issuers that are a part of the same controlled group. These commenters stated that issuers with shared ownership should not be able to exploit their corporate structure to avoid consumer protections and effectively circumvent the otherwise applicable maximum duration limits for STLDI coverage. Some commenters suggested that extending the limitation to include all issuers in the same controlled group could help address concerns regarding STLDI sold through associations,[186] as associations might be positioned to facilitate the issuance of stacked STLDI policies from different subsidiaries of the same controlled group. One commenter stated that members of the same controlled group should have the data and member-tracking capabilities to know if a consumer has purchased an STLDI policy within the 12 months from another issuer within the same controlled group.

The Departments agree with commenters that supported the Departments' authority to address the stacking loophole as part of the definition of renewal or extension for purposes of the new interpretation of "limited-duration." As stated in the preamble to the 2023 proposed rules, the Departments are concerned that stacking practices lengthen the duration of STLDI coverage without offering the benefits of comprehensive coverage that is subject to Federal consumer protections and requirements for comprehensive coverage, including limitations on medical underwriting, the prohibition of preexisting condition exclusions, and the prohibition on coverage rescissions. Using the stacking loophole, issuers could enroll consumers in multiple consecutive STLDI policies that together provide coverage for 12 months (or longer), in effect circumventing the rules related to maximum duration and making it more challenging for consumers to distinguish STLDI from comprehensive coverage.[187]

As discussed in section III.A.1 of this preamble, the Departments have clear authority to interpret and implement the Code, ERISA, and the PHS Act as they do here. This includes the authority to issue regulations on STLDI to define it and set standards that distinguish it from individual health insurance coverage. Providing a definition for what a renewal or extension means in the context of the new interpretation of "limited-duration" is included within this authority and is not a constraint on consumer behavior. Instead, the definition and standards, as proposed and finalized, apply to health insurance issuers that elect to offer STLDI. Further, consumers will continue to have access to STLDI plans that are generally exempt from the Federal consumer protections and requirements for comprehensive coverage.[188] Neither the proposed rules nor these final rules sought to extend to STLDI or otherwise make changes with respect to the applicability of those consumer protections and requirements.

After considering comments, the Departments are finalizing as proposed that a renewal or extension, for purposes of applying the interpretation of "limited-duration" under the new STLDI definition adopted in these final rules, includes the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance. Subsequent sales to the same policyholder by the same issuer within the same 12-month period will be treated comparably to renewals for purposes of calculating and applying the limited-duration standard.

The Departments also agree that extending the definition of renewal or extension for purposes of applying the new interpretation of "limited-duration" to limit stacking of STLDI policies sold by issuers that are members of the same controlled group is appropriate and necessary. This prevents issuers from circumventing the maximum duration standards in the revised Federal STLDI definition adopted in these final rules by marketing policies of one member of a controlled group to policyholders enrolled in STLDI coverage of another member of the controlled group, keeping that policyholder enrolled in STLDI coverage for more than the maximum allowed coverage period. The final rules therefore provide that for purposes of applying the new interpretation of "limited-duration," a

[184] 827 F.3d 70, 74 (D.C. Cir. 2016).

[185] *See* section III.A.4 of this preamble.

[186] For further discussion on STLDI sold through associations, *see* section III.A.5 of this preamble.

[187] 88 FR 44596 at 44612–44613 (July 12, 2023).

[188] While STLDI is generally not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage, the agent and broker compensation disclosure and reporting requirements in section 2746 of the PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

renewal or extension includes the term of a new STLDI policy, certificate, or contract of insurance offered by either the same issuer or, if the issuer is a member of a controlled group, any other issuer that is a member of the same controlled group. For these purposes, a "controlled group" means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code. HHS uses a similar definition of "controlled group" for purposes of the guaranteed renewability rules and QHP issuer standards, and the Departments anticipate the usage is familiar to health insurance issuers.[189]

The relevant metric to calculate whether the duration of coverage sold by the same issuer or any other issuer that is a member of the same controlled group to the same policyholder satisfies the revised Federal interpretation of "limited-duration" in these final rules is the total number of days of coverage (either consecutive or non-consecutive) that the policyholder is enrolled in an STLDI policy with the same issuer or any other issuer that is a member of the same controlled group. That calculation applies regardless of whether the coverage is a renewal or extension under the same policy, certificate, or contract of insurance, or if it involves the issuance of a new STLDI policy, certificate, or contract of insurance to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance.

Several commenters requested that the Departments expand the approach to address the stacking loophole to also include the sale of STLDI policies by unaffiliated issuers. These commenters were concerned that stacking will continue through policies sold by multiple issuers. Some commenters questioned whether focusing only on stacking policies sold by the same issuer achieves the goals described in the proposed rules because consumers could still stack STLDI purchased from different issuers. One commenter expressed concern that the proposed limitation on stacking by only the same issuer would harm consumers because seeking STLDI policies from multiple issuers would result in the coverage offering different networks and benefits. A commenter that supported extending the approach to address the stacking loophole to also apply to STLDI policies sold by unaffiliated issuers shared that some States prohibit consumers from enrolling in STLDI for more than 3 months in a 12-month period, regardless of issuer. Another commenter, who was supportive of the general concept of limiting stacking across issuers, cautioned that it would be exceedingly difficult for issuers to implement a limit on the sale of multiple STLDI policies by different issuers within the same year at this time. Some commenters who supported the extension of the approach to unaffiliated issuers explained that such an approach could be implemented by issuers certifying, by consumer attestation, or by another similar mechanism, that the policyholder has not purchased STLDI coverage from any issuer within the previous 12-month period, while others suggested that the Departments create a safe harbor for issuers that require consumers to sign attestations regarding previous STLDI coverage.

While the Departments appreciate these comments and recommendations, the Departments decline to extend the definition of renewal or extension for purposes of applying the revised interpretation of "limited-duration" to limit stacking of policies issued by unaffiliated issuers. As explained in the proposed rules, the Departments are cognizant of the administrative burden for issuers of tracking and ensuring compliance with such a prohibition.[190] However, States may choose to further address issuer stacking practices, such as by prohibiting stacking across issuers not within the same controlled group.

One commenter suggested the Departments limit an issuer's ability to issue subsequent STLDI policies to members of the same household. The Departments did not propose to limit an issuer's ability to sell subsequent STLDI policies to members of the same household and decline to adopt such a limitation in these final rules. Members of the same household may need temporary, stopgap coverage at different times over a 12-month period. Limiting the ability of members of the same household to purchase STLDI coverage would remove flexibility for consumers and unnecessarily complicate their health insurance enrollment process because issuers would have to determine whether members of the same household have enrolled in any STLDI coverage during the previous 12-month period each time any member of the household enrolls in STLDI, which could create an administrative burden on issuers. Furthermore, whereas limiting stacking across affiliated issuers in the same controlled group will prevent issuers from using their corporate structure to circumvent the rules related to maximum duration, it is not apparent to the Departments that limiting stacking across unaffiliated issuers or different members of the same household accomplishes any similar goal. Finally, the administrative burden of tracking members of the same household may outweigh any potential benefit of restricting the sale of multiple STLDI policies to individuals who reside in the same household.

Some commenters requested that the Departments affirm that consumers are entitled to renewal guarantees that might be offered by an STLDI issuer. As explained in the preamble to the 2018 final rules, renewal guarantees generally permit a policyholder, when purchasing their initial insurance contract, to pay an additional amount in exchange for a guarantee that the policyholder can elect to purchase, for periods of time following the expiration of the initial contract, another policy or policies at some future date, at a specific premium that would not require any additional underwriting.[191] The Departments affirm that the final rules do not address renewal guarantees. However, the Departments acknowledge that the revisions to the Federal definition—including the provision that requires counting the term of a new STLDI contract issued by the same issuer or, if the issuer is a member of a controlled group, any other issuer that is a member of the same controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, contract, or certificate of insurance toward the total maximum duration of STLDI—would limit the guarantees that such instruments may be able to provide.[192]

3. Sales and Marketing Practices

In the 2023 proposed rules, the Departments expressed concerns about reports of aggressive and deceptive sales and marketing practices related to STLDI where STLDI is marketed as a substitute for comprehensive coverage, despite being exempt from most of the Federal individual market consumer protections and requirements for comprehensive coverage.[193] [194] The

[189] *See* 45 CFR 147.106(d)(3) and (4) (providing an exception to market withdrawal under guaranteed renewability regulations) and 156.20 (defining an "issuer group" for purposes of QHP issuer standards).

[190] 88 FR 44596 at 44646 (July 12, 2023).

[191] *See* 83 FR 38219, 38220 (Aug. 3, 2018).

[192] While the Departments may be limited in their ability to take an enforcement action with respect to transactions involving products or instruments that are not health insurance coverage, the Departments may have the authority to regulate the coverage issued pursuant to such a product or instrument.

[193] *See* 88 FR 44596 at 44613 (July 12, 2023).

[194] The agent and broker compensation disclosure and reporting requirements in section 2746 of the

Continued

Departments solicited comments on additional ways to help consumers distinguish between comprehensive coverage and STLDI. In particular, the Departments requested comments on ways to prevent or otherwise mitigate the potential for direct competition between comprehensive coverage and STLDI during the open enrollment period for comprehensive individual health insurance coverage.[195]

Many commenters agreed that STLDI deceptive marketing practices have caused many consumers to confuse STLDI with comprehensive coverage. These commenters stated that these misleading marketing practices often attract younger, healthier consumers who may not realize how limited STLDI coverage is until faced with out-of-pocket costs. Commenters observed that studies indicate that STLDI has been aggressively and deceptively marketed to consumers especially during the open enrollment period for comprehensive individual health insurance coverage,[196] which has left consumers at increased risk of purchasing plans that do not meet their medical needs. Commenters also noted that the population of individuals affected by States resuming Medicaid eligibility redeterminations due to the end of the FFCRA's Medicaid continuous enrollment condition has been vulnerable to these practices. Commenters highlighted evidence of salespeople neglecting to tell consumers that they may be eligible for subsidized ACA plans, asserting that an individual's health needs would be covered by an STLDI plan despite plan documents contradicting these assertions, or misstating an STLDI plan's coverage of certain preexisting conditions. Commenters also included examples of deceptive marketing practices (some of which were identified during secret shopper studies), such as marketing materials with images of activities for which coverage of associated injuries are excluded, marketing materials with logos of well-known issuers that are not affiliated with the STLDI being sold, or websites selling STLDI that include the words "Obamacare" or "ACA."

One commenter suggested that the Departments should monitor and limit marketing of STLDI that is conducted in a manner that may lead consumers to unwittingly enroll in STLDI. The commenter stated that multiple States have already implemented prohibitions against aggressive and deceptive marketing of STLDI products to protect individuals. The commenter stated that a Federal prohibition on such marketing tactics would ensure that people are aware of the most affordable and comprehensive health coverage options available to them, are not exposed to deceptive marketing practices, and are able to avoid potentially catastrophic gaps in coverage.

Other commenters expressed concern regarding the sale of STLDI over the telephone and internet. The commenters cited studies showing an increase in sales over the telephone and internet since the 2018 final rules. Commenters stated that although telephone and internet sales are convenient for consumers, the incentives to provide reliable customer service are low. Commenters noted that such sales methods are prone to abuse and make it hard for consumers to get concrete, verifiable answers about the product they are being sold before they buy it. Other commenters suggest that sellers of STLDI be reviewed for compliance with laws enforced by the Federal Trade Commission that prohibit deceptive marketing practices. Some commenters suggested that marketers of STLDI sold over the telephone or internet should be required to provide a clear warning to consumers about the true coverage terms prior to the conclusion of a sale.

Some commenters encouraged the Departments to collaborate with State departments of insurance to combat misleading marketing practices. Commenters noted that the expansion of STLDI following the 2018 final rules has presented challenges for State regulators attempting to monitor the applicable State market and protect potential consumers against deceptive marketing practices. Commenters suggested that the Departments, in collaboration with the Federal Trade Commission and the Federal Bureau of Investigation, should investigate and stop lead generators and sales agents who use deceptive marketing techniques through websites, social media, phone calls, and other means.

Several commenters urged the Departments to establish a Federal prohibition on the sale of STLDI during the annual open enrollment period for comprehensive individual health insurance coverage. Commenters cautioned that when STLDI is marketed and sold during the annual individual market open enrollment period, the potential for consumer confusion is particularly acute. Commenters explained that sellers take advantage of the annual open enrollment period when more consumers are shopping for comprehensive individual health insurance coverage to push them into products that are not comprehensive and argued that halting sales of STLDI during this period would decrease consumer confusion and facilitate access to comprehensive coverage. Another commenter stated that legitimate needs for STLDI coverage may arise at any time of year and recommended that if the Departments place restrictions on the sale of STLDI during the annual individual market open enrollment period, those restrictions should be limited to the sale of products with a January 1 effective date.

Another commenter suggested that the Departments explicitly prohibit Federal and State Exchanges from linking to or advertising STLDI. The commenter stated that HHS should also impose a similar requirement on agents and brokers to prohibit side-by-side advertising of STLDI or other non-compliant plans on the same web page as individual health insurance coverage that is subject to the Federal consumer protections and requirements for comprehensive coverage.

One commenter suggested that the Departments consider prohibiting the offering of higher broker commissions for the sale of STLDI than commissions for the sale of comprehensive coverage, arguing that this type of prohibition could significantly decrease the financial incentive for agents and brokers to encourage consumers to purchase STLDI over comprehensive coverage and help reduce direct competition between these two types of products.

Some commenters encouraged the Departments to invest in and take steps to increase consumer education and enrollment assistance activities that could improve consumer understanding of the differences between comprehensive coverage and STLDI.

Other commenters suggested placing requirements on agents and brokers or the consumer to better ensure consumers understand the differences between STLDI and comprehensive coverage. For example, one commenter suggested that the Departments require agents and brokers to sign an attestation that the information given to the consumer by the agent or broker spells out in plain language the terms of the STLDI coverage and acknowledges that the consumer understands the limitations. The commenter asserted this would help ensure that underserved communities and patients with chronic medical conditions who struggle to find

PHS Act apply to health insurance issuers offering individual health insurance coverage or STLDI.

[195] *See* 88 FR 44596 at 44613–44614 (July 12, 2023).

[196] Government Accountability Office (2020). "Private Health Coverage: Results of Covert Testing for Selected Offerings," available at: *https://www.gao.gov/products/gao-20-634r.*

affordable health insurance options are not targeted by unscrupulous sales and marketing tactics. Another commenter urged the Departments to adopt the same disclosure and consent requirements applicable to agents, brokers, and web-brokers assisting consumers in a Federally-facilitated Exchange or State Exchange using the Federal platform for agents, brokers, and web-brokers assisting consumers purchasing STLDI.[197] One commenter suggested that the Departments require a statement for consumers to sign acknowledging that the coverage does not meet the minimum standards required under the ACA and does not provide equivalent Federal consumer protections.

The Departments appreciate these comments and suggestions and will take them into consideration in any future regulations or guidance defining STLDI. In addition, the Departments appreciate the recommendations regarding steps that the Departments can take outside of rulemaking to educate consumers about their health coverage options and limit the possibility that consumers inadvertently purchase STLDI when shopping for comprehensive coverage. HHS has already taken steps separate from these final rules to limit the potential for individuals to inadvertently purchase an STLDI plan when shopping for a qualified health plan and will consider additional opportunities to do so. *HealthCare.gov*, the platform for the Federally-facilitated Exchanges and State Exchanges using the Federal platform, neither links to nor advertises STLDI.[198] In addition, for the Federally-facilitated Exchanges and State Exchanges using the Federal platform, direct enrollment entities [199] are generally required to use three different website pages to display and market coverage—one for qualified health plans offered through the Exchange, one for individual health insurance coverage offered outside the Exchange, and one for any other products, including STLDI.[200] Direct enrollment entities participating in the Federally-facilitated Exchanges and State Exchanges using the Federal platform must also limit marketing of non-QHPs, such as STLDI, during the Exchange eligibility application and QHP selection process.[201] In its proposed rule entitled "Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO–OP) Program; and Basic Health Program," HHS proposed to apply these requirements to direct enrollment entities operating in State Exchanges and to web-brokers that assist with or facilitate enrollment in coverage in a manner that constitutes enrollment through the State-based Exchanges.[202]

4. Notice

In the preamble to the 2023 proposed rules, the Departments explained that the notice is important to help consumers distinguish between comprehensive coverage and STLDI and ensure that consumers are aware of the limitations of STLDI.[203] The Departments proposed to amend the existing STLDI notice to further clarify the differences between STLDI and comprehensive coverage and identify options for consumers to obtain comprehensive coverage in concise, understandable language that would be meaningful to them.[204] The Departments proposed to apply the amendments to the notice to all STLDI policies sold or issued on or after the effective date of the final rules and to existing STLDI policies for notices provided upon renewal or extension on or after the effective date of the final rules.[205]

In the 2023 proposed rules, the Departments proposed that the notice must be displayed (in either paper or electronic form) prominently in at least 14-point font, on the first page of the policy, certificate, or contract of insurance (including for renewals or extensions), in any marketing and application materials provided in connection with enrollment in such coverage, including on websites that advertise or enroll individuals in STLDI, and in any enrollment and reenrollment materials that are provided at or before the time an individual has the opportunity to enroll or reenroll in coverage (including on any website used to facilitate reenrollment in STLDI).[206]

In these final rules, the Departments are finalizing the revised notice with modifications to implement feedback from comments and consumer testing, improve consumer comprehension of the notice, and further distinguish between STLDI and comprehensive coverage. As discussed in section III.A.6 of this preamble, the revised notice must be provided with respect to both new and existing STLDI for coverage periods (including renewals or extensions) beginning on or after September 1, 2024.

Some commenters were generally opposed to revisions to the notice standard. These commenters expressed concern that the Federal revised notice may not comport with notices that State legislatures and regulators create, often in consultation with consumer advocates and State insurance experts. A commenter expressed concern that the information about ACA coverage in the proposed notice would confuse the average person shopping for health coverage. Another commenter suggested that the Departments defer to the NAIC

[197] *See* 45 CFR 155.220 for standards applicable to agents and brokers and web-brokers who assist qualified individuals, qualified employers, or qualified employees enrolling in qualified health plans.

[198] *See* section 1311(d)(2) of the ACA, which generally prohibits an Exchange from making available any health plan that is not a qualified health plan. *See also* CMS, Frequently Asked Questions on Reuse of Exchange for Ancillary Products (March 29, 2013), available at: *https://www.cms.gov/cciio/resources/files/downloads/ancillary-product-faq-03-29-2013.pdf*.

[199] "Direct enrollment entity" means an entity that an Exchange permits to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by 45 CFR 155.220(c)(3), 45 CFR 155.221, or 45 CFR 156.1230. 45 CFR 155.20.

[200] 45 CFR 155.221(b)(1).

[201] 45 CFR 155.221(b)(3).

[202] 88 FR 82510, 82568 and 82562 (Nov. 24, 2023) ("Consistent with §§ 156.1230(b)(1) and (2), to directly enroll consumers in a manner that is considered to be through the Exchange, QHP issuer DE entities are required to comply with the applicable requirements in § 155.221 . . . In this rulemaking, we propose to extend these FFE requirements to also apply them to QHP issuer DE entities in State Exchanges. As proposed to be applied in these State Exchanges, QHP issuer DE entities would similarly be required to provide consumers with correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the Exchanges, and insurance affordability programs. In addition, QHP issuer DE entities in State Exchanges would also be required to refrain from marketing or conduct that is misleading (including by having a DE website that the State Exchange determines could mislead a consumer into believing they are visiting the Exchange's website), coercive, or discriminates based on race, color, national origin, disability, age, or sex . . . Finally, we propose . . . to extend the current web-broker FFE standard of conduct established at § 155.220(j)(2)(i) to also apply to web-brokers assisting consumers in State Exchanges, and consequently to these State Exchanges. Section 155.220(j)(2)(i) requires agents, brokers, or web-brokers that assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through an FFE, or assist individuals in applying for APTCs and CSRs for QHPs sold through an FFE, must provide consumers with correct information, without omission of material fact, regarding the FFEs, QHPs offered through the FFEs, and insurance affordability programs . . . and refrain from marketing or conduct that is misleading (including by having a DE website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex.")

[203] 88 FR 44596 at 44614 (July 12, 2023).

[204] *Id.* at 44614–44618.

[205] *Id.* at 44618–44619.

[206] *Id.* at 44614–44616.

and State regulatory experts who are currently drafting minimum standards for STLDI products. A commenter suggested that States should have the option to substitute their own required disclosure language in place of the Federal mandated language and that notice provisions should only be applicable if a State has no comparable notice provisions.

Another commenter shared a study asserting that the revised notice did not substantially improve consumer understanding of STLDI and that any notice should be of short length because most consumers have trouble understanding lengthy explanations that tend to present multiple concepts in the same notice. Other commenters supported the proposed revisions to the notice standard and agreed that the revisions would help educate consumers about the differences between comprehensive coverage and STLDI before a decision is finalized about health coverage in a way that would alleviate downstream concerns about applicable benefits and costs.

The Departments agree that it is important to provide consumers with concise, accurate information to evaluate insurance products so that consumers may make informed decisions about health insurance coverage. The Departments sought to address potential confusion caused by the notice by requesting comments on the proposed notice standard and conducting consumer testing. Based on current research highlighting deceptive marketing practices and consumer confusion, [207] [208] [209] the Departments are of the view that it is necessary and appropriate for issuers of STLDI to disclose key differences between comprehensive coverage and STLDI before completing the sale or renewal so consumers can make informed decisions. The revised notice standard under these final rules will help clarify the differences between STLDI and comprehensive coverage. As the Departments agree that the revisions to the notice standard alone will not protect consumers from deceptive marketing practices, revisions to the notice standard are being finalized in tandem with revisions to the definitions of the terms "short-term" and "limited-duration." The Departments disagree with and decline to adopt the suggestion that the notice should not be part of the Federal definition of STLDI.

With respect to concerns about the lack of State input in the revisions to the notice standard, the Departments consulted plain language experts, conducted consumer testing, and considered comments on the 2023 proposed rules from State regulators, consumer advocates, and other interested parties. The Departments therefore disagree that there was a lack of State input. The Departments concluded that a uniform Federal notice best furthers the Departments' interest in ensuring that information is communicated to consumers to enable them to identify and distinguish STLDI from comprehensive coverage. Therefore, the Departments decided not to specify that the revised notice would be applicable only if a State has no comparable notice provision. In addition, these final rules do not prevent States from requiring additional language be included with the notice for purposes of State law or prohibit issuers from including additional language in their notices. Policies that do not include the language in the revised notice under these final rules will not be considered STLDI coverage, and therefore will not qualify for the exception for STLDI from the definition of individual health insurance coverage for purposes of Federal law.

One commenter alleged that the revised notice standard raised First Amendment concerns because the notice violates the First Amendment's prohibition on compelled speech. The commenter argued that the revised notice standard constitutes a content-based restriction and is not justified because it is not narrowly tailored to serve a compelling government interest.

The Departments disagree with this commenter. The rules do not require the provision of a notice, but instead simply provide that coverage offered without such a notice would not qualify as STLDI and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. Moreover, as discussed in section III.B.1 of this preamble, required disclosures of factual, uncontroversial information in commercial speech are subject to more deferential First Amendment scrutiny and have been upheld where the disclosure requirement reasonably relates to a government interest, and is not unjustified or unduly burdensome.[210] Regardless, the Departments believe that the revised notice standard would pass muster under any form of First Amendment scrutiny.

The Departments have a substantial, and even compelling, government interest in combatting deceptive marketing practices by ensuring consumers are informed about the key differences between STLDI and comprehensive coverage, are aware of their option to purchase comprehensive coverage, and have access to resources for additional information about the range of available health coverage options so consumers can make informed choices. As discussed in section II.B of this preamble, this is currently of particular importance due to significant changes in market conditions and in the legal landscape and low health literacy amid widespread deceptive marketing practices that play on consumer confusion about the benefits and limitations of STLDI. The revised notice communicates factual information to consumers about the differences between STLDI and comprehensive coverage and explains how consumers can find resources when consumers have questions about the different coverage options. Finally, the revised notice is reasonably related to, and narrowly tailored to, the government's interest in informing consumers about STLDI coverage, and combating deceptive marketing practices and potential sources of misinformation, by directing consumers to appropriate resources to learn more about the range of available health coverage options. The notices do not include irrelevant or superfluous information unrelated to these interests. Accordingly, these final rules serve substantial government interests.

[207] For one example of deceptive marketing practices, *see* Federal Trade Commission (2022). "FTC Action Against Benefytt Results in $100 Million in Refunds for Consumers Tricked into Sham Health Plans and Charged Exorbitant Junk Fees," available at: *https://www.ftc.gov/news-events/news/press-releases/2022/08/ftc-action-against-benefytt-results-100-million-refunds-consumers-tricked-sham-health-plans-charged.*

[208] Palanker, Dania and Kevin Lucia (2021). "Limited Plans with Minimal Coverage Are Being Sold as Primary Coverage, Leaving Consumers at Risk," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2021/limited-plans-minimal-coverage-are-being-sold-primary-coverage-leaving-consumers-risk.* (Noting that fixed indemnity insurance may be "bundled" with other non-comprehensive insurance products in such a way that "the plans look like comprehensive coverage" while still offering limited benefits). *See also* Palanker, Dania, JoAnn Volk, and Maanasa Kona (2019). "Seeing Fraud and Misleading Marketing, States Warn Consumers About Alternative Health Insurance Products," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/seeing-fraud-and-misleading-marketing-states-warn-consumers-about-alternative-health.*

[209] Government Accountability Office (2020). "Private Health Coverage: Results of Covert Testing for Selected Offerings," available at: *https://www.gao.gov/products/gao-20-634r.*

[210] The U.S. Supreme Court recognized this standard of scrutiny in *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626 (1985) ("*Zauderer*") and later confirmed it in *National Institute of Family and Life Advocates* v. *Becerra*, 138 S. Ct. 2361, 2372, 2376 (2018) ("*NIFLA*").

In addition, the revised notice standard is not unjustified, unduly burdensome, or insufficiently tailored to the interests described previously. As stated in the preamble to the 2023 proposed rules, the Departments are concerned about consumers who are at risk of significant financial liability if they enroll in STLDI that exposes consumers to high health care costs that are not covered by their STLDI policy. The language on the Federal revised notice includes factual, uncontroversial information. The Departments consulted plain language experts, conducted consumer testing, and considered comments on the proposed revised notice to ensure the language was factual, easy to read, and understandable. Furthermore, the revised notice standard does not unduly burden issuer speech because issuers remain free to communicate with consumers about their coverage using any methods of communication they choose. As discussed in section V.B.2.d of this preamble, the Departments estimate that the cost to issuers of displaying the revised notice will be relatively low, because the Departments have adopted static language that issuers do not have to tailor to the policy or State of sale. For the reasons discussed previously, the Departments are of the view that requiring STLDI issuers to provide a notice that provides factual information to consumers prior to when the consumers purchase coverage is reasonably related to the government's stated interests in ensuring consumers can distinguish STLDI and comprehensive coverage and are informed of options to purchase comprehensive coverage, should the consumer wish to obtain such coverage. The information required to be disclosed is clearly identified and has a direct nexus to that legitimate government interest. Finally, the revised notice standard is narrowly tailored to inform consumers about the limitations of STLDI and to combat deceptive marketing practices and potential sources of misinformation by directing consumers to appropriate resources to learn more about their health coverage options. The notice does not include irrelevant or superfluous information unrelated to informing and directing consumers to appropriate resources.

The Departments sought comments on whether the proposed placement for the notice substantially improves the likelihood that consumers have a meaningful opportunity to review the notice and their health coverage options before applying for, enrolling in, or reenrolling in STLDI, as well as any practical or logistical barriers to providing this notice as proposed. In particular, the Departments sought comments from members of underserved communities, and organizations that serve such communities, on whether the language accessibility, formatting, and content of the notice sufficiently mitigate barriers that exist to ensuring all individuals can read, understand, and consider the full range of their health coverage options.[211]

Most commenters supported the proposed placement of the notice on the first page of any policy, certificate, or contract of insurance (including for renewals and extensions), website used to facilitate enrollment (or reenrollment) in STLDI, and marketing and application materials provided in connection with enrollment in STLDI, because the benefits of simplifying access to the notice far outweighs any associated burden of including the information in these locations. One commenter suggested that issuers should have the flexibility to put the notice for renewals on a separate document and not on the face page of the policy, certificate, or contract of insurance because some States require pre-approval of notice provisions. Another commenter supported the notice being provided in the same format that sales of STLDI are conducted, since misleading marketing often occurs when STLDI is not sold in person and consumers are given limited time to contemplate their insurance choices before being pressured to choose a product. For example, if enrollment occurs over the telephone, the commenter suggested the seller should be required to read the notice to the consumer and record their acknowledgement, or if the enrollment occurs via the internet, a prominent notice should be featured during the accompanying online sign-up process. Other commenters recommended that the Departments require audio and video advertisements to include an audio version of the notice within the first 10 seconds of any advertisement of STLDI coverage. Another commenter suggested that telephone solicitors, brokers or agents making sales calls, or in-person sales should be required to inquire as to the consumer's preferred language through a qualified language translator or language telephone line. Commenters also suggested that the notice be provided in multiple common languages other than English that are spoken in the United States in a manner that is culturally appropriate, readable, and clear so that consumers can make appropriate coverage decisions. Commenters highlighted the importance of the notice being accessible to individuals with disabilities.

The Departments are finalizing the standard for the notices to be prominently displayed on the first page of applicable materials[212] in at least 14-point font, as proposed. Because ensuring that consumers understand any limitations of what they are purchasing is of utmost importance, provision of the notice should not be saved until the time of enrollment when consumers may feel pressured to sign up and effectuate coverage instead of restarting their search for a different insurance product. The Departments agree with commenters that the need for consumers to have easy access to the notice during enrollment and reenrollment outweighs the burden associated with placement of the notice on the first page of applicable materials. The Departments further agree with commenters that if the STLDI policy is sold online or electronically then the notice should be communicated in the same format as the sale. Further, consistent with the proposal in the 2023 proposed rules, the placement standard under these final rules extends the notice to websites that advertise or offer the opportunity to enroll (or reenroll) in STLDI. Although these final rules provide that the notice must be prominently displayed in any marketing materials provided in connection with enrollment (or reenrollment) in STLDI, the Departments decline to require audio and video advertisements include an audio version of the notice within the first 10 seconds of any advertisement of STLDI coverage. The Departments did not include a proposal on audio and video advertisements in the 2023 proposed rules and therefore decline to address such other types of communication formats in these final rules.

The Departments agree that it is important that the notice be accessible and understandable to individuals with limited English proficiency. While the Departments did not propose and are not finalizing language access standards

[211] 88 FR 44596 at 44617 (July 12, 2023).

[212] The applicable materials on which the STLDI notice must be prominently displayed (in either paper or electronic form) are the first page of the policy, certificate, or contract of insurance (including for renewals or extensions), any marketing and application materials provided in connection with enrollment in such coverage, including on websites that advertise or enroll individuals in STLDI, and in any enrollment and reenrollment materials provided at or before the time an individual has the opportunity to enroll or reenroll in coverage (including on any website used to facilitate reenrollment in STLDI).

specific to these notices as part of this rulemaking, the Departments remind plans and issuers that they are required to comply with other State and Federal laws establishing accessibility and language access standards to the extent applicable. For example, recipients of Federal financial assistance must comply with Federal civil rights laws that prohibit discrimination. These laws may include section 1557 of the Affordable Care Act,[213] title VI of the Civil Rights Act of 1964,[214] section 504 of the Rehabilitation Act of 1973,[215] and the Americans with Disabilities Act of 1990.[216] Section 1557 and title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services such as written translation of written content in paper or electronic form into languages other than English. Sections 1557 and 504 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Additionally, section 508 of the Rehabilitation Act of 1973 requires that information provided through information and communication technology also must be accessible to individuals with disabilities, unless certain exceptions apply.

In the 2023 proposed rules, the Departments requested comment on two potential formats for the revised notice standard [217] (Notice A and Notice B).

The proposed STLDI notice (Notice A) was as follows:

BILLING CODE 4830–01–P

Notice to Consumers About Short-Term, Limited-Duration Insurance

IMPORTANT: This is short-term, limited-duration insurance. This is temporary insurance. **It isn't comprehensive health insurance.** Review your policy carefully to make sure you understand what is covered and any limitations on coverage.

- This insurance might not cover or might limit coverage for:
  - preexisting conditions; or
  - essential health benefits (such as pediatric, hospital, emergency, maternity, mental health, and substance use services, prescription drugs, or preventive care).
- You won't qualify for Federal financial help to pay for premiums or out-of-pocket costs.
- You aren't protected from surprise medical bills.
- When this policy ends, you might have to wait until an open enrollment period to get comprehensive health insurance.

Visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325) to review your options for comprehensive health insurance. If you're eligible for coverage through your employer or a family member's employer, contact the employer for more information. Contact your State department of insurance if you have questions or complaints about this policy.

An alternative proposed STLDI notice (Notice B) was as follows:

[213] 42 U.S.C. 18116.
[214] 42 U.S.C. 2000d *et seq.*
[215] 29 U.S.C. 794.
[216] 42 U.S.C. 12101 *et seq.*
[217] 88 FR 44596 at 44616–44617 (July 12, 2023).

WARNING

This is not comprehensive insurance. This is short-term, limited-duration insurance.

This plan has fewer protections than comprehensive insurance options you can find on HealthCare.gov.

This Insurance	Insurance on HealthCare.gov
• May deny you coverage if you have a preexisting condition	• You cannot be denied coverage because of a preexisting condition
• There may be no limit to the amount you have to pay out-of-pocket for care	• The most you have to pay out-of-pocket for essential health benefits in a year is limited
• You will not qualify for Federal financial help to pay your premiums and out-of-pocket costs	• You may qualify for Federal financial help to pay your premiums and out-of-pocket costs
• You may not have access to all essential health benefits, including: pediatric, hospital, emergency, maternity, mental health, and substance use disorder services, prescription drugs, and preventive care	• You will have access to all essential health benefits, including: pediatric, hospital, emergency, maternity, mental health, and substance use disorder services, prescription drugs, and preventive care

Questions?

- For more info about comprehensive coverage, visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325).
- For more info about your employer's coverage, or a family member's employer coverage, contact the employer.

For questions or complaints about this policy, contact your State department of insurance.

The Departments received comments in support of both notice formats. Some commenters supported implementing the format of Notice A because they found the bulleted format easier to read and more understandable than a chart. Other commenters supported implementing the format of Notice B because they were of the view that the format is easier to follow and has more concise language. A commenter stated that consumers understand information better that is presented in charts. Another commenter suggested that the Departments design a notice format that would allow issuers to check boxes next to relevant provisions. Other commenters recommended that the Departments conduct consumer testing of the content and presentation of the notices through focus groups or surveys to ensure the notices are understandable. These commenters stated that notices should be tested with multiple audiences, particularly given current disparities in health insurance literacy rates and concerns for individuals with limited English proficiency and with disabilities.

HHS consulted plain language experts and engaged in consumer testing as part of the consideration of comments on the revised notice. Based on the testing of Notice A and Notice B, feedback from plain-language experts, along with consideration of comments on the revised notice, the Departments are finalizing the table format used in Notice B, with content modifications that are discussed in detail this section. Consumer testing revealed that the table format, comparing key features of STLDI and insurance offered through *HealthCare.gov*, helped consumers best distinguish between STLDI coverage and comprehensive coverage, and understand the differences between such coverage types.

After taking into account feedback from the comments, consulting with plain-language experts, and conducting consumer testing, the Departments are finalizing the following language for the notice to improve readability and effectiveness of the notice:

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

The Departments took into consideration all comments received on the notice. As mentioned in this section, following an initial review of the comments, HHS performed consumer testing to evaluate the effectiveness and readability of different messages and notice formats, including messages or changes to the proposed revised notice recommended by commenters. These final rules revise the content of the proposed notice to better inform consumers considering purchasing STLDI about the differences between STLDI and comprehensive coverage, support informed coverage purchasing decisions, and promote readability. The

revised notice balances including information about STLDI with readability and length so that consumers will be more likely to read and understand the notice.

The Departments sought comments on whether additional changes to the notice language would improve readability or further help individuals distinguish STLDI from comprehensive coverage, and whether there are practical or logistical barriers that would present challenges to compliance with the new proposed notice standard. The Departments solicited comments on all aspects of the proposed revisions to the notice standard, including whether to add a website link and telephone number for *HealthCare.gov*, and the proposed placement of the notice in the marketing, application, and enrollment (or reenrollment) materials, including the extension of the notice provision to websites that advertise or offer the opportunity to enroll (or reenroll) in STLDI and on the associated administrative burden for issuers, agents, brokers, or others who will be involved in providing the notice to consumers.

Many commenters suggested specific changes to the content of the revised notice standard. A commenter requested that the notice be displayed in highly readable fonts such as a Sans Serif font in a 14-point font to improve the readability of the notice. Some commenters suggested that the notice include additional information to explain what it means that STLDI is exempt from most Federal consumer protection laws. Some commenters recommended that the notice include a statement that STLDI coverage commonly conducts post-claims underwriting and may deny claims for chronic health conditions, surgeries, and other common services. A commenter recommended that the Departments add language warning consumers about the possibility of recissions because STLDI issuers often engage in post-claims chart review to search for signs of an undisclosed preexisting condition and thereby rescind coverage. The commenter recommended that the notice state: "This insurance may rescind or retroactively cancel your coverage and not pay claims based on your medical history." The Departments are finalizing the requirement that the notice be in 14-point font size. While the final rules do not include a requirement that the notice be displayed in a specific font, the Departments would not consider the notice to be prominently displayed unless the font used is clear and readable. The revised notice standard will give issuers the flexibility to use a font that aligns with the format of their policies. In addition, the Departments revised the content of the chart based on comments and consumer testing. As a result, the chart clarifies that STLDI is not required to meet the Federal standards for comprehensive coverage and might not cover chronic health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health and substance use. In contrast, the notice does not specifically caution consumers that STLDI might conduct post-claims underwriting, or post-claims recissions. The Departments had to balance providing useful information that clarifies the differences between STLDI and comprehensive coverage and the readability, length, and effectiveness of the notice. The differences highlighted in the notice were selected primarily because consumer testing showed they were more effective at helping consumers distinguish between STLDI and comprehensive coverage than other options considered.

Some commenters suggested the notice address the 10 categories of essential health benefits [218] and state explicitly which essential benefits are not covered. Other commenters requested that the notice address coverage for certain types of items or services, such as maternity services, habilitative and rehabilitative services, and devices, so that consumers fully understand what coverage could be missing when purchasing STLDI. While the Departments agree that it is important to highlight for consumers that essential health benefits might not be covered by an STLDI policy, the notice only highlights a few categories of essential health benefits, including prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, and physical therapy. The Departments had to balance the importance of notifying consumers of the types of benefits that might not be covered, with the importance of not overcrowding the notice so that the notice is easy to read and understand.

Some commenters supported the notice including information about where consumers can access additional information about comprehensive coverage options, including referencing *HealthCare.gov* or the State Exchange website where the consumer resides, including when the coverage is sold by associations. Some commenters requested that the notice explain what subsidies may be available for consumers that enroll in coverage on the Exchanges instead of STLDI to increase transparency of the costs to consumers. Some commenters suggested adding information on the timing of the annual individual market open enrollment period to underscore the differences between STLDI and comprehensive individual health insurance coverage and help consumers plan their transition to Exchange coverage. Commenters also suggested that providing information on special enrollment periods for those losing Medicaid or employer coverage would further clarify consumers' coverage options. Additionally, given the potential for varied open enrollment or special enrollment periods across different States, a commenter recommended adding language saying, "Because State Based Exchanges may have different enrollment timelines, if you lose coverage always check your eligibility on *Healthcare.gov* or your State Based Exchange for possible enrollment options."

The Departments agree with commenters that it is important for the notice to include information about where consumers can access additional information about comprehensive coverage options, and are finalizing a notice standard that includes information about *HealthCare.gov*. Through this website, consumers in States with a Federally-facilitated Exchange or State Exchange using the Federal platform can purchase comprehensive coverage, and consumers in States with a State Exchange can get directed to the State Exchange. In addition, *HealthCare.gov* provides additional information about comprehensive coverage that might help consumers further distinguish STLDI coverage from comprehensive coverage, and may help consumers better understand the notice. The Departments considered including in the revised notice standard additional details, as suggested by commenters, about open enrollment, special enrollment periods, and subsidies. However, the Departments are concerned about the length these topics could add to the notice, and the burden associated with customizing the notices to include enrollment time frames which can vary slightly from State to State. After consideration of the comments, the Departments are finalizing the revised notice standard without information on these topics. However, the Departments note that information on each of these topics is available on *HealthCare.gov*, and the notice directs consumers to

[218] *See* section 1302 of the ACA, and 45 CFR 156 subpart B (defining essential health benefits).

HealthCare.gov for additional information on health coverage options.

Some commenters suggested additional or alternative language to focus consumers' attention or to convey key points. A commenter suggested using the phrase "Important Notice—Please Read Carefully" as the title to better catch the attention of consumers and inform them that this is important information they should consider prior to purchase. Another commenter supported the use of the word "WARNING" in capital letters as a heading in the notice for clarity. A commenter suggested adding to the introductory notice language, "This plan has fewer protections, provides fewer benefits, and has higher out of pocket costs than comprehensive insurance options you can find on *HealthCare.gov*." A commenter suggested that the Departments replace the last sentence of the introductory paragraph with something very close to the following in bold text, "You may be able to get much better coverage for less money (with tax credits) through a health insurance exchange even outside of open enrollment." A commenter suggested that the Department should change the heading of the second column of the comparison table from "Insurance on *HealthCare.gov*" to "Comprehensive Insurance on *Healthcare.gov*." One commenter encouraged the Departments to remove the statement that STLDI is not comprehensive coverage because of a study that indicated that 95 percent of STLDI plans provide comprehensive coverage. A commenter suggested that the Departments revise "You won't qualify for [F]ederal help to pay for premiums or out-of-pocket costs," to "Most people qualify for tax credits that will lower out of pocket costs if they purchase coverage that meets certain [F]ederal requirements. For more information, visit [this website]." In addition, the Departments could create a website to link consumers to clear information, the commenter stated.

The Departments took into consideration comments that suggested alternative language to include in the introductory paragraph. Based on consumer testing, the Departments are finalizing the revised notice standard with the heading, "IMPORTANT," instead of "WARNING." The Departments are of the view that "IMPORTANT" is sufficient to draw attention to the notice. In addition, the Departments revised the introductory paragraph to clarify that STLDI and insurance options on *HealthCare.gov* are not the only insurance options that might provide comprehensive coverage. While employer coverage is not included in the table, the Departments finalized the revised notice standard with a bullet point reminding consumers that have access to employer coverage to contact that employer about coverage options. The Departments are of the view that suggested additions to the introductory paragraph add content that is already accounted for in the table section of the notice. The Departments are not revising the notice heading for the second column. The heading, "Insurance on *HealthCare.gov*," effectively communicates that the column applies to insurance options available on *HealthCare.gov*.

Some commenters provided recommendations for ways to enhance consumers' understanding of the notice. One commenter suggested that the Departments define key terms used in the notice and use alternate language to indicate that the coverage is "comprehensive" because some consumers believe that it means the best or most expensive coverage that most consumers do not need. A commenter discouraged the use of terms "may" and "might" because they fall short of conveying how STLDI does not meet Federal standards.

The Departments considered comments and worked with plain language experts to ensure that the revised notice standard is written in plain language that maximizes readability for the average consumer. While consumer testing revealed that consumers did not always understand terms used in the notice (including the term "comprehensive"), the testing showed that consumers were still able to distinguish between STLDI and comprehensive coverage, based on the notice. Therefore, the Departments are of the view that defining key terms is not critical to the effectiveness of the notice and are finalizing the revised notice standard without defining key terms. In addition, the Departments will use the term "might" to preface certain rows in the table. It is important to include the term "might" to ensure that the content in the table accurately describes all STLDI coverage, as some STLDI might voluntarily, or under State law, provide the consumer protections listed in the notice.

Some commenters were in support of including the name and State of domicile of the issuer, name and State of domicile of the association (if applicable), website, and telephone number for the State department of insurance tailored to each STLDI policy in the notices included in marketing, application, and renewal materials to help consumers access regulators and consumer advocacy resources that can assist consumers regarding questions or concerns about their policies. Commenters stated that STLDI coverage filed in another State or sold through an out-of-State association should be required to include in the notice both the contact information of the insurance regulator in the State in which the consumer resides and the State in which the plan is filed, to aid in maintaining accountability for issuers and associations selling these insurance products. Commenters stated that access to such information will assist consumers in receiving accurate information about insurance products to make informed decisions about coverage and should be made available in the preferred language of individuals and families. Commenters argued that State regulators often have difficulty monitoring and regulating STLDI sold through out-of-State associations, the associations may attempt to operate outside the reach of the State in which the STLDI is sold, and consumers may be unaware of what State has regulatory authority over the product they are purchasing.

Other commenters were opposed to including State-specific information in the notices because the information would be of limited benefit to consumers and unnecessarily increase the administrative burden and costs for issuers. Another commenter suggested that the Departments provide a link to the directory of State insurance departments that the NAIC maintains.

In developing the proposed revised notice language, the Departments sought to balance the goals of distinguishing STLDI from comprehensive coverage and combatting deceptive marketing practices, as well as reducing misinformation by directing consumers to appropriate resources, with the need to provide a concise, understandable notice that would be meaningful and useful to consumers.[219] The Departments understand commenters' concerns regarding the burden associated with customizing notices to include State-specific information. However, the Departments also recognize the value of including State-specific information, such as appropriate contact information. After consideration of comments and the results of consumer testing, the Departments are finalizing changes to the notice to incorporate uniform language as part of the required content for the revised notice standard that directs individuals to an NAIC web page

[219] *See* 88 FR 44596 at 44614–44615 (July 12, 2023).

where they can find the contact information for the applicable State regulatory agency. This approach avoids adding an administrative burden on issuers to tailor the notice for each plan depending on the domicile of each consumer. In the case of STLDI sold by out-of-State associations, the link to the NAIC web page would provide consumers with access to contact information for State regulators in the State where the consumer purchased the STLDI coverage as well as the State where the STLDI is issued. Although this is a link to a non-United States Government website, the Departments are including this link in the notice because it allows consumers to access State-specific contact information, without requiring plans and issuers to customize the notice. The Departments cannot attest to the accuracy of information provided on the NAIC web page or any other linked third-party site. The NAIC link is provided for reference only and the inclusion in the notice of a link to a non-United States Government website does not constitute an endorsement by the Departments. Also, the privacy protections generally provided by United States Government websites do not apply to third-party sites.

In addition, as described earlier in this section, the Departments incorporated static language as part of the content for the revised notice standard finalized in these final rules that direct individuals to *HealthCare.gov* where individuals can navigate to their State's Exchange or get information about different types of health coverage options. This approach is intended to balance the desire to ensure individuals can access State-specific information with not increasing the burden on issuers associated with the development of customized notices that provide State-specific contact information. Since the Departments are not including State-specific or association-specific contact information as part of the revised notice standard, the Departments decline to specify a certain agency's contact information that should be included for products that are filed in multiple States.

The preamble to the 2023 proposed rules explained that the Departments were considering whether to add a statement to the notice describing the maximum permitted length of STLDI under the Federal definition, explaining that coverage cannot be renewed or extended beyond the maximum allowable duration, and explaining that the length of STLDI may be shorter subject to State law. The Departments sought comments on this approach, including how best to clearly and concisely communicate such information to consumers, including how to address the bifurcated applicability dates with respect to the proposals around the maximum allowed length; whether such information is already included elsewhere in the plan documents; and on the associated administrative burden for issuers, agents, brokers, or others who would be involved in providing the notice to consumers. The Departments also sought comments on whether information about the maximum allowed length of new or existing STLDI and options regarding renewal and extensions would be included in enrollment materials (or reenrollment materials) provided to enrollees as part of the normal course of business.

Commenters generally supported adding a statement to the notice describing the maximum allowed length of STLDI under Federal and State rules, where applicable. One commenter requested that the Departments add, "coverage is intended to last for 3 months, if you enroll in the plan you may have to wait until the next open enrollment period to enroll in comprehensive coverage." A commenter suggested adding a sentence to the notice after the second sentence of the introductory paragraph that says, "Coverage cannot last beyond 4 months or even less depending on the State in which you live." This minimally increases the length of the notice while informing the consumer that the policy cannot be renewed beyond 4 months or a shorter period depending on the State in which the consumer resides, the commenter stated.

While the Departments appreciate that information on maximum duration may be useful to consumers, the Departments remain concerned about how to clearly and concisely communicate such information to consumers using static language, without creating confusion for consumers if the duration of their policy differs from the maximum duration standards in the notice—for example, because of the bifurcated applicability dates,[220] shorter maximum durations allowed under State law, or the specifics of their policy. Given these concerns and based on consumer testing and consultation with plain language experts, the Departments are finalizing the notice without adding information on the maximum permitted length of STLDI. Since States have the flexibility to enact a different maximum permitted length of STLDI, including a standardized maximum permitted length in the revised notice standard may confuse consumers. The Departments are also mindful of limiting the amount of information provided on the notice for readability and comprehension and are of the view that the burden on issuers of requiring issuers to tailor their notices to each State outweighs the potential benefits of adding more language to the notice to capture State-specific information on the maximum permitted length for the STLDI policy. In addition, the Departments anticipate that information on the maximum allowed length of the STLDI coverage is included in the policy, certificate, or contract of insurance, and that options for renewal and extensions are typically included in enrollment materials (or reenrollment materials) provided to enrollees as part of the normal course of business.

The Departments solicited comments on whether it would be beneficial to consumers to require issuers to include language in the notice that clearly informs consumers that the notice is an officially required document, such as "This notice is required by Federal law." One commenter suggested that including such a statement would further validate the importance of the notice and accentuate the caution warranted when considering purchasing STLDI, while another commenter argued that the statement would add length to the notice and is not critical for consumers' understanding of their rights. Consumer testing revealed that some testers found the inclusion of that phrase at the bottom of the notice helpful and reported that it made the information on the notice seem more legitimate, other consumers stated this statement suggested that the STLDI policy was endorsed by the Federal Government. After consideration of the comments and results from consumer testing, the Departments are finalizing the notice without the inclusion of a statement that the notice is required by Federal law. The Departments are of the view that any potential benefit of including the language is outweighed by the risk that some consumers will interpret the statement as a Federal endorsement of the policy.

5. Short-Term, Limited-Duration Insurance Sold Through Associations

In section III.A.5 of the preamble to the 2023 proposed rules, the Departments explained that they understand most sales of STLDI occur through group trusts or associations that are not related to employment

[220] *See* section III.A.6 of this preamble for discussion of the STLDI applicability dates finalized in these final rules.

(sometimes referred to as individual membership associations) [221] and solicited comments on what steps, if any, can be taken to support State oversight of STLDI sold to or through associations.[222] Under these arrangements, out-of-State issuers file STLDI products for approval in one State and then sell the same policies in other States through an association, many times with few requirements on consumers to participate in the association, other than payment of association dues. State regulators have reported that they often lack the authority to track sales of policies made through out-of-State associations and are unable to approve or regulate such policies when offered for sale by issuers that are not licensed by their State. Further, as explained in section III.A.V of the preamble to the 2023 proposed rules, the Departments have received feedback that many issuers take advantage of the ambiguity about which State's jurisdiction applies to the STLDI they sell to avoid State regulation.[223] For example, one study found that in a review of 34 policy brochures for STLDI, 28 of the brochures included references to associations.[224] Consumers may not understand that some STLDI marketed in their States are not regulated by their State and do not include State-specific consumer protections.

The Departments received comments agreeing that association-based STLDI coverage is often used as a vehicle to avoid local State regulation, with one commenter stating that such coverage is increasing in prevalence for employers with 10 or fewer employees. Commenters explained that because these association products are sold in States in which they are not registered, States have limited ability to protect their consumers from hidden fees and limited benefits. Nevertheless, some commenters asserted that States are best positioned to oversee the marketing of association-based STLDI coverage. Some commenters encouraged the Departments to work with States and the NAIC to improve oversight of products sold through out-of-State associations including collecting and sharing data and clarifying State authority to regulate these arrangements on behalf of their residents. Another commenter urged the Departments to consider additional enforcement mechanisms to ensure that STLDI issuers are not selling STLDI products in States in which they are not approved and ensure that consumers have recourse to file complaints when necessary.

As with the current regulatory definition of STLDI, the provisions of these final rules apply to STLDI sold to or through associations. As explained in the preamble to the 2023 proposed rules, coverage that is provided to or through associations, but not related to employment, and is sold to individuals, either as certificate holders or policyholders, is not group coverage under section 9832 of the Code, section 733(b)(4) of ERISA, and section 2791(b)(4) of the PHS Act.[225] If the coverage is offered to an association member other than in connection with a group health plan, the coverage is considered coverage in the individual market under Federal law, regardless of whether it is considered group coverage under State law. Thus, any health insurance sold to individuals through a group trust or association, other than in connection with a group health plan, or sold to a group trust or association to the extent the insurance is intended to cover association members who are individuals, must meet the definition of STLDI at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103, or else be considered individual health insurance coverage that is subject to all the Federal individual market consumer protections and requirements for comprehensive coverage.

The Departments are aware that some group trusts and associations have also marketed STLDI policies to employers as a form of employer-sponsored coverage. As explained in section I.C of this preamble, there is no provision excluding STLDI from the Federal definition of group health insurance coverage.[226] Thus, any health insurance that is sold to or through a group trust or association in connection with a group health plan and which purports to be STLDI would in fact be group health insurance coverage and must comply with the Federal consumer protections and requirements for comprehensive coverage applicable to the group market. Failure to meet those requirements could result in penalties for employers offering such coverage.[227]

The Departments did not propose changes specific to association-based STLDI coverage and are not finalizing any such changes in these final rules. The Departments will continue to work closely with States, both individually and through the NAIC, to support State oversight and enforcement efforts of STLDI offered through associations.

6. Applicability Dates

In the 2023 proposed rules, the Departments proposed applicability dates for the proposed amendments to the Federal definition of STLDI that distinguish between new and existing STLDI under 26 CFR 54.9833–1, 29 CFR 2590.736, and 45 CFR 146.125 and 148.102. The Departments also proposed a technical amendment to 26 CFR 54.9833–1, 29 CFR 2590.736, and 45 CFR 146.125 (regarding applicability dates) to remove outdated language. The Departments proposed the technical amendment would apply to all coverage (that is, both new and existing STLDI) as of the effective date of the final rules.

The Departments did not receive any comments on the proposed applicability dates for the technical amendments and are finalizing them as proposed.

For new STLDI sold or issued on or after the effective date of the final rules, the Departments proposed that the amendments to the definition of STLDI would apply for coverage periods beginning on or after such date. For STLDI sold or issued before the effective date of the final rules (including any subsequent renewal or extension consistent with applicable law), the Departments proposed that the current Federal definition of such coverage would continue to apply with respect to the maximum allowable duration. Therefore, under the proposed rules, existing STLDI could continue to have an initial contract term of less than 12 months and a maximum duration of up to 36 months (taking into account any renewals or extensions), subject to any limits under applicable State law.

The Departments proposed that the amendments to the notice provision at paragraph (2) of the proposed definition of "short-term, limited-duration insurance" in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103 would apply for coverage periods beginning on or after the effective date of the final rules, regardless of whether the coverage was sold or issued before, on, or after the effective date of the final rules.

[221] *See* 88 FR 44596 at 44618 (July 12, 2023).

[222] *Id.*

[223] *Id.*

[224] *Id.* (citing Curran, Emily, Dania Palanker, and Sabrina Corlette (2019). "Short-term Plans Sold Through Out-of-State Associations Threaten Consumer Protections," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/short-term-health-plans-sold-through-out-state-associations-threaten-consumer-protections.*)

[225] 88 FR 44596 at 44618 (July 12, 2023) (citing 45 CFR 144.102(c)).

[226] *See* section 2791(b)(5) of the PHS Act, which excludes STLDI from the definition of "individual health insurance coverage".

[227] Section 4980D of the Code.

The Departments sought comments on whether the proposed revised notice standard should apply only to new STLDI or should apply to both new STLDI and existing coverage upon renewal or extension, and whether the application of the proposed revised notice standard to existing STLDI should instead be delayed until January 1, 2025, or some other date. The Departments sought comments on whether all STLDI policies and any renewals or extensions of such coverage, including existing coverage sold or issued prior to the effective date of the final rules, should instead end upon the effective date of the final rules or some other date. The Departments also sought comments on whether an applicability date that would provide a longer transition period for consumers with policies, certificates, or contracts of STLDI sold or issued before the effective date of the final rules could help alleviate any potential market disruption. In addition, the Departments sought comments on whether it would be more reasonable for all STLDI policies, and any renewals or extensions of such coverage in effect before the date the final rules are published, to end before January 1, 2025, or some other date.

Only a few commenters commented on the applicability date for new STLDI policies. One commenter stated that it is critically important for consumers that the proposed amendments to the Federal definition of STLDI take effect as soon as possible for new STLDI policies to better inform consumers about the differences between STLDI and comprehensive coverage and protect consumers from deceptive marketing practices. A few commenters suggested that the Departments delay the applicability date for new STLDI policies, with recommended dates ranging from between 90 days and 12 months after the effective date of the final rules. Commenters recommended providing this additional time because STLDI products have already been filed and approved for 2024 and issuers need more time to evaluate plan designs, update system processes, re-file policy forms with State regulators and complete other administrative tasks.

The Departments agree that an applicability date of 75 days following publication of these final rules might cause challenges for some States and issuers as they move to revise plan designs and file new policy forms that comply with the Federal definition of SLTDI under these final rules. The Departments are mindful of the administrative obstacles identified by commenters and are of the view that providing more time to comply with the revised Federal definition of STLDI will be beneficial both to issuers and States. However, the Departments are also mindful of the caution from commenters that the potential for consumer confusion is particularly acute when STLDI is marketed and sold during the annual individual market open enrollment period. Although these final rules do not prohibit the sale or marketing of STLDI during the individual market open enrollment period, the Departments are of the view that the potential for consumer confusion about whether they are considering purchasing an STLDI plan or comprehensive coverage will be substantially lessened if the final rules go into effect for new STLDI policies before the beginning of the next individual market open enrollment period.[228] Therefore, after consideration of comments, these final rules provide that the new definition of STLDI will apply to new STLDI policies, certificates, or contracts of insurance for coverage periods beginning on or after September 1, 2024.[229] This applicability date will provide issuers and States with more time to come into compliance with these final rules for new STLDI policies. It will also allow uninsured consumers who enroll in a new STLDI policy on or after September 1, 2024, to bridge the gap to when new comprehensive coverage purchased during the next individual market open enrollment period would begin. The Departments decline to extend the applicability for new STLDI policies further to ensure an end to the marketing of STLDI with a longer maximum allowed length prior to the beginning of open enrollment for the 2025 individual market plan year.[230]

The Departments received some comments on the applicability date with respect to the maximum allowable duration for existing STLDI (including renewals and extensions). A few commenters requested that the revised maximum allowable duration apply to existing policies as soon as possible. These commenters stated that agents and brokers may attempt to steer as many consumers as possible into policies that are subject to the 2018 final rules prior to the applicability date for new policies, locking consumers into less protective coverage with a longer duration, and potentially destabilizing the risk pools for individual health insurance coverage. Commenters stated that this is particularly concerning as more consumers are shopping for health coverage as States resume Medicaid eligibility redeterminations due to the end of the FFCRA's Medicaid continuous enrollment condition. Another commenter stated that the Departments should apply the same applicability date for the maximum duration to new and existing policies because having a different applicability date for new and existing STLDI could create confusion for consumers and issuers. However, a different commenter suggested that the proposed applicability date for the revised maximum duration to apply to existing coverage would minimize confusion for currently enrolled consumers. One commenter supported the proposed applicability date for the revised maximum duration to apply to existing STLDI, as the dates allow issuers to honor their contractual obligations while avoiding unnecessary disruptions in coverage. Another commenter suggested aligning the applicability date for the revised maximum duration to apply to existing STLDI with the existing term or the start of the subsequent plan year for Exchange coverage, whichever comes first, and providing a 60-day special enrollment period to consumers whose coverage ends after the individual market open enrollment period. Other commenters recommended that the Departments postpone the applicability date for the revised maximum duration for STLDI to apply to existing policies to accommodate the end of the initial contract term, but prevent renewals or extensions to strike a balance between avoiding disruption of current plans and prolonging the harms of the maximum permitted duration under the current Federal definition of STLDI. These commenters also suggested this alternative approach would simplify the application of the revised maximum duration for STLDI coverage under the final rules. Other commenters suggested setting a different fixed applicability date for the revised maximum duration for SLTDI to apply to existing policies that aligns with the start of the individual market open enrollment period for plan years 2025 or 2026.[231]

[228] The next individual market open enrollment period begins on November 1, 2024. *See* 45 CFR 155.410(e)(4)(i).

[229] For new STLDI policies, the new maximum duration standards and the revised notice established in these final rules will apply for coverage periods beginning on or after September 1, 2024.

[230] The individual market open enrollment period for plan year 2025 begins on November 1, 2024. *See* 45 CFR 155.410(e)(4)(i).

[231] The individual market open enrollment periods for plan years 2025 and 2026 begins on November 1, 2024, and November 1, 2025, respectively. *See* 45 CFR 155.410(e)(4)(i).

The Departments appreciate the need to implement the changes to the revised maximum duration for STLDI as soon as practical to mitigate the risk of consumers mistakenly enrolling in STLDI in lieu of comprehensive coverage. At the same time, the Departments recognize that some consumers who are already enrolled in STLDI purchased such coverage with the understanding it would continue for a given period of time, consistent with the current Federal definition of STLDI and applicable State law. Such individuals may also have purchased coverage with the expectation that they could renew coverage, consistent with the current Federal definition and applicable State law. While the Departments want to balance avoiding prolonging the harms of a longer maximum permitted duration, to minimize disruption and confusion for individuals who purchased or were enrolled in STLDI prior to the effective date of the final rules, the Departments are finalizing the proposal to permit such individuals to remain covered under STLDI for the maximum initial contract term, as well as for renewals and extensions, to the extent permitted under the 2018 final rules, subject to any limits under applicable State law. Although the Departments are not applying the revised maximum duration for STLDI to renewals or extensions of existing coverage, consumers can opt not to renew or extend their coverage prior to reaching the maximum duration permitted for such coverage. The Departments are not persuaded by the concern that having different applicability dates for the revised maximum duration for new and existing coverage will create confusion for consumers and issuers. As noted by one commenter, allowing individuals with existing coverage to continue their coverage for the maximum duration allowed when they purchased STLDI may instead minimize confusion and align with the consumer's expectations when they purchased the coverage. Confusion for consumers who newly enroll in STLDI coverage on or after September 1, 2024, is likely to be minimal since they would not be eligible to purchase, renew, or extend an STLDI policy for the longer maximum duration permitted under the 2018 final rules. The Departments are of the view that the different applicability dates will also create minimal confusion and burden for issuers, which already need to track which STLDI policies are eligible for renewal or extension and for how long. The Departments are finalizing the applicability date for existing STLDI policies with respect to the maximum allowable duration for such coverage as proposed.

As discussed in section III.A.1 of this preamble, HHS declines to create a special enrollment period for individuals to enroll in individual health insurance coverage at the expiration of their STLDI coverage. However, nothing in Federal law would prevent an individual from discontinuing their STLDI coverage prior to its expiration date to align the end of their STLDI coverage with the start of individual health insurance coverage or other comprehensive coverage.

Some commenters supported applying the proposed revised notice to new STLDI sold or issued on or after the effective date of the final rules and to existing coverage upon renewal or extension. Another commenter recommended that the Departments apply the proposed amendments to the notice only to new STLDI sold or issued on or after the effective date of the final rules and to existing coverage starting 12 months after the publication of these final rules. Some commenters expressed concern that the proposed applicability dates for the revised STLDI notice did not provide enough time for implementation in States that require notices be submitted to the State department of insurance for review or approval.

The Departments agree with commenters that the revised notice should promptly apply to both new and existing (upon renewal or extension) STLDI coverage to alert all consumers who are considering purchasing or renewing STLDI to the differences between comprehensive coverage and STLDI. The notice is key to providing consumers with the information necessary to make an informed decision about the range of available coverage options. However, the Departments recognize that it would be burdensome on issuers to finalize three separate applicability dates (that is, for the notice provisions, for the maximum duration standards applicable to new policies, and for the maximum duration standards applicable to existing policies). In addition, the Departments acknowledge that issuers in some States may need to engage with their State regulator prior to implementing the new notice. After consideration of comments, the Departments are finalizing a delayed applicability date for the revised notice to align with the delayed applicability date finalized in these final rules for new STLDI coverage. Specifically, the revised notice specified in these final rules must be provided for new STLDI policies sold or issued on or after September 1, 2024, and with respect to existing coverage, upon renewal or extension that occurs on or after September 1, 2024.

B. Independent, Noncoordinated Excepted Benefits Coverage

In the group market, for hospital indemnity or other fixed indemnity insurance to qualify as an excepted benefit, among other criteria, the insurance must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100/day), regardless of the amount of expenses incurred. In contrast, under the current individual market regulations, fixed indemnity insurance can pay on a per-period and/or per-service basis and be considered an excepted benefit. In the 2023 proposed rules, HHS proposed to realign the individual market regulations with the group market regulations, which would require hospital indemnity or other fixed indemnity insurance to pay a fixed dollar amount per day (or per other period) of hospitalization or illness to be considered an excepted benefit in the individual market, consistent with the group market rules.

The Departments also proposed additional payment standards for hospital indemnity or other fixed indemnity insurance to be considered an excepted benefit in the group market. HHS proposed parallel payment standards for fixed indemnity excepted benefits coverage in the individual market. Under the 2023 proposed rules, fixed indemnity excepted benefits would be required to be paid regardless of the items or services received, actual or estimated amount of expenses incurred, severity of illness or injury experienced, or any other characteristics particular to a course of treatment received by a covered participant, beneficiary, or enrollee.

The preamble to the 2023 proposed rules also explained that the Departments are aware that some employers offer employees a "package" of coverage options that include a non-excepted benefit group health plan that provides minimal coverage (for example, coverage of preventive services only) with fixed indemnity insurance that provides benefits associated with receiving a broad category of other services for which coverage is excluded from the non-excepted benefit group health plan. The Departments explained they are concerned that some employers are attempting to circumvent the Federal consumer protections and requirements for comprehensive coverage that

otherwise apply to group health plans by offering most benefits associated with receiving health care services under fixed indemnity insurance labeled as an excepted benefit, potentially leaving employees without crucial Federal consumer protections.

To address this concern and clarify the Departments' interpretation of the requirement that hospital indemnity and other fixed indemnity insurance must offer "noncoordinated" benefits to be considered an excepted benefit, the Departments proposed to add a new example to the group market regulations to reflect that the prohibition on coordination of benefits is not limited to only those situations involving a formal coordination-of-benefits arrangement. The proposed example illustrated a scenario with a fixed indemnity insurance policy and a group health plan maintained by the same plan sponsor in which a formal coordination-of-benefits arrangement was not present but there was nonetheless coordination between the provision of benefits under the fixed indemnity insurance policy and an exclusion of benefits under the group health plan. HHS proposed to apply the same interpretation of the noncoordination requirement to individual market fixed indemnity excepted benefits coverage.[232]

The Departments proposed a consumer notice for group market fixed indemnity benefits coverage. HHS also proposed amendments to the existing consumer notice for individual market fixed indemnity excepted benefits coverage. These proposals would ensure that fixed indemnity excepted benefits coverage is properly identified in marketing, application, and enrollment (or reenrollment) materials as fixed indemnity excepted benefits coverage, rather than comprehensive health insurance that is subject to Federal consumer protections, which would help a prospective enrollee distinguish between fixed indemnity excepted benefits coverage and comprehensive coverage options. With these proposals, the Departments aimed to support informed consumer choice by promoting consumer awareness of the limitations of fixed indemnity excepted benefits coverage and to help prevent consumers from mistakenly purchasing such coverage as an alternative to or replacement for comprehensive coverage.

The Departments received many comments in response to all of these proposals. These final rules adopt the new notice for fixed indemnity excepted benefits coverage offered in the group market and update the existing notice for such coverage offered in the individual market. In response to comments and consumer testing, the Departments have modified the content and applicability date of the notice, as discussed in more detail later in sections III.B.1 and III.B.3 of this preamble. However, to provide more time to study the issues and concerns raised in comments, these final rules do not address any other provision of the 2023 proposed rules relating to fixed indemnity excepted benefits coverage (with the exception of certain technical amendments to the HHS individual market regulation proposed in the 2023 proposed rules, as discussed in more detail later in section III.B.2 of this preamble). The Departments remain concerned with practices that appear to circumvent Federal consumer protections and requirements and intend to address the other proposals for hospital indemnity or other fixed indemnity insurance in future rulemaking, taking into account comments received on these issues.

No inference should be drawn from the decision not to finalize the proposed payment standards or noncoordination example as part of these final rules, and plans and issuers should not assume that current market practices that are inconsistent with the 2023 proposed payment standards or noncoordination example comply with the existing Federal regulations that apply to fixed indemnity excepted benefits coverage.

To the contrary, many comments received in response to the 2023 proposed rules underscored the Departments' concerns that hospital indemnity or other fixed indemnity insurance is being used by some issuers, plan sponsors, plans, agents, and brokers to circumvent the Federal consumer protections and requirements applicable to comprehensive coverage, while offering products that blur the lines between the two types of coverage. The Departments remain concerned about the deceptive marketing and sale of hospital indemnity and other fixed indemnity insurance, including the creation of hospital indemnity or other fixed indemnity insurance with detailed fee schedules. These types of fixed indemnity insurance products are not consistent with the traditional role of hospital or other fixed indemnity insurance serving as a form of income or wage replacement that the statutory exception was intended to cover. Instead, they mimic comprehensive coverage, without providing the Federal consumer protections or meeting the requirements applicable to comprehensive coverage. This leaves individuals who mistakenly purchase such coverage in lieu of comprehensive coverage without critical consumer protections, exposing them to significant health and financial risk.

Similarly, the Departments remain concerned about the practice of offering a "package" of coverage options that includes a non-excepted benefit plan that provides minimal coverage (such as coverage only for preventive services)[233] plus a fixed indemnity insurance policy that provides benefits associated with a broad range of items and services for which the other coverage maintained by the employer (or, in the individual market, maintained by the same issuer) excludes benefits. The Departments remain concerned that these plan designs are structured as coordinated arrangements to circumvent the Federal consumer protections and requirements for comprehensive coverage that otherwise would apply. This is particularly concerning if the employers, employees, or individuals are under the impression or are misled to believe that their two coverages, when combined, provide comprehensive coverage, and they therefore forgo pursuing other available options that would provide comprehensive coverage. The Departments intend to address these issues in future rulemaking.

The Departments emphasize that, to be considered fixed indemnity excepted benefits coverage under the current Federal group market regulations, the benefits must be paid only on a per-period basis. Under this standard, the Departments expect that fixed indemnity excepted benefit coverage would not be designed with fee schedules that, in effect, provide benefits for specific items and services, such as wellness screening exams or prescription drugs, rather than wage or income replacement. The Departments are aware that some issuers merely affix a "per day" term to benefits for specific items and services, such as $50 per

[232] Consistent with the interpretation and application of the statutory requirement that fixed indemnity excepted benefits coverage in the individual market must be offered on a noncoordinated basis, HHS proposed to modify the requirement at current 45 CFR 148.220(b)(4)(ii) to specify that benefits under fixed indemnity excepted benefits coverage must be paid with respect to an event without regard to whether benefits are provided with respect to such an event under any other health coverage "maintained by the same issuer.". HHS is not finalizing this proposed modification to the individual market noncoordination standard at this time.

[233] The Departments note that such an arrangement would not be treated as providing minimum value if it failed to provide substantial coverage of inpatient hospital services and physician services. 26 CFR 1.36B–6; 45 CFR 156.145.

blood test per day. As stated in the preamble to the 2023 proposed rules, when analyzing whether a policy, certificate, or contract of insurance is subject to the Federal consumer protections and requirements for comprehensive coverage, the Departments will look past the label used to examine whether the policy, certificate, or contract of insurance qualifies as an excepted benefit or whether it is comprehensive coverage that is subject to the Federal consumer protections and requirements applicable to such coverage. The Departments encourage State regulators to take a similar approach and intend to work with States to ensure that issuers comply with relevant requirements.

1. Notices

To ensure that consumers purchasing fixed indemnity excepted benefits coverage are aware of the type of coverage they are purchasing, including the limitations of the coverage, and that it is not mistakenly purchased as an alternative or replacement for comprehensive coverage, the Departments proposed to require a consumer notice be prominently displayed when offering fixed indemnity excepted benefits coverage in the group market, in alignment with the existing requirement to provide such a notice when offering fixed indemnity excepted benefits coverage in the individual market. The Departments proposed that if a plan or issuer provides the required group market notice in accordance with the provisions in the 2023 proposed rules, the obligation to provide the notice would be satisfied for both the plan and issuer.

In developing the proposed notice for the group market and revising the notice for the individual market, the Departments sought to balance two goals. One goal was to combat potential sources of misinformation by directing consumers to appropriate resources to learn more about comprehensive coverage and understand how that coverage differs from fixed indemnity excepted benefits coverage. The other goal was to provide a concise, understandable notice that would be meaningful to, and actionable by, consumers.

HHS also proposed technical amendments reorganizing the regulatory text to move the provision regarding the placement and materials on which the notice must appear for fixed indemnity excepted benefits coverage in the individual market, as well as amendments to the content and formatting for the notice itself, to align with the proposal to adopt a notice for the group market.

Many commenters supported requiring prominent display of the proposed consumer notice in both markets to help consumers distinguish fixed indemnity excepted benefits coverage from comprehensive coverage, make individuals aware of opportunities to purchase comprehensive coverage, and inform them of possible eligibility for subsidies to purchase comprehensive coverage. Commenters strongly supported disclosures to explain the limited nature of fixed indemnity excepted benefits coverage. One commenter stated that there is a need for a model consumer notice that is succinct, clear, and prominent, especially because prior efforts have not stopped abusive marketing tactics. One commenter stated that clear, consistent, and consumer-friendly disclosures are the best mechanism to ensure fixed indemnity policies are marketed in a clear and appropriate manner, particularly if consumers are purchasing coverage online. Another commenter stated that the proposed notice language was consistent with current industry standards and expressed support for even stronger disclosure language.

The Departments agree with these commenters. By requiring a prominent disclosure notice to consumers who are considering enrolling or reenrolling in individual or group market fixed indemnity excepted benefits coverage, the Departments aim to ensure that consumers are informed about the type of coverage they are purchasing, and thereby reduce the potential for consumers to mistakenly enroll in such coverage as their primary source of coverage and to increase consumer understanding of the differences between fixed indemnity excepted benefits coverage and comprehensive coverage.

The Departments also agree with commenters that the notices should provide information to consumers in a clear and concise manner regarding opportunities to purchase comprehensive coverage, especially regarding their possible eligibility for subsidies. As noted in the preamble to the 2023 proposed rules and in section III.A.1 of this preamble, individuals belonging to underserved populations often experience greater health challenges, as well as greater challenges accessing and using health care services, compared to the general population, including worse health outcomes, higher rates of chronic conditions, lower access to health care, and more frequent experiences of discrimination in health care settings.[234] Members of these populations may be particularly vulnerable to misinformation or misleading or aggressive sales tactics. A notice can help combat misinformation and misleading or aggressive sales practices by helping consumers distinguish between comprehensive coverage and fixed indemnity excepted benefits coverage.

For these reasons, as well as research identifying disparities in health insurance literacy among underserved populations and people with incomes below the FPL,[235] the Departments proposed, and are finalizing in these rules, the adoption of a consumer notice that must be provided when offering fixed indemnity excepted benefits coverage in the group market. HHS is also finalizing revisions to the existing consumer notice that must be provided when offering fixed indemnity excepted benefits coverage in the individual market. In the Departments' view, these notices will help ensure that all consumers, including those in underserved communities, have the necessary information to make an informed choice after considering and comparing the full range of health coverage options available to them.

Some commenters stated that changes or additional notices were not necessary because existing notice provisions are sufficient. One commenter stated that although they agree that consumers need to understand what they are buying, the proposed notice provisions are not necessary since State-required consumer warnings already exist, and a Federal notice is not the proper mechanism to promote consumer education or awareness. Some commenters suggested that existing fixed indemnity insurance policies should be exempt from any notice requirement since the consumer has already enrolled and presumably knows what they purchased.

The Departments disagree with commenters that stated that existing notice provisions are sufficient, that the

[234] *See* CMS Office of Minority Health (2022). "The Path Forward: Improving Data to Advance Health Equity Solutions," available at: *https://www.cms.gov/files/document/path-forwardhe-data-paper.pdf.*

[235] Edward, Jean, Amanda Wiggins, Malea Hoepf Young, and Mary Kay Rayens (2019). "Significant Disparities Exist in Consumer Health Insurance Literacy: Implications for Health Care Reform," *Health Literacy Research and Practice*, available at: *https://pubmed.ncbi.nlm.nih.gov/31768496/. See also* Villagra, Victor and Bhumika Bhuva (2019). "Health Insurance Literacy: Disparities by Race, Ethnicity, and Language Preference," *The American Journal of Managed Care*, available at: *https://www.ajmc.com/view/health-insurance-literacy-disparities-by-race-ethnicity-and-language-preference.*

proposed notice provisions are unnecessary because State-required notices exist, and that a Federal notice is not the proper mechanism to promote consumer education or awareness. The existing Federal notice provision only applies to the individual market, leaving consumers in the group market potentially uninformed about the limited nature of their fixed indemnity excepted benefit coverage and unaware of resources to learn more about other coverage options. In addition, while some State-required notices may exist, they are not mandated nationwide. In the Departments' view, a Federal notice provision is the proper mechanism to promote consumer education or awareness by conveying a consistent message at or before the time a consumer has an opportunity to enroll in the fixed indemnity excepted benefit coverage in the individual and group markets. Without such a notice consumers may be left unaware or uninformed, because notices may not be provided at all, or would be provided at the plan's or issuer's discretion. Other mechanisms, such as public service announcements, would not ensure that information has been provided to every prospective consumer. Additionally, the Departments are of the view that requiring issuers to provide the consumer notice contemporaneously with marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage (rather than separately from the application process or after a product has already been purchased) will ensure that consumers are made aware of the type of coverage they are considering, are made aware of information resources at their State Department of Insurance, and are provided with options for purchasing comprehensive coverage at the time when they most need this information to support their decision-making process.

The Departments also do not agree that existing policies should be exempt from the applicable notice. Although a consumer may have already purchased fixed indemnity excepted benefit coverage in the past, the consumer may not have been aware of the limitations of such coverage or available comprehensive coverage options and may wish to evaluate all of their options before reenrolling. Therefore, the Departments are finalizing the proposal to provide the group market notice at or before the time participants are given the opportunity to enroll or reenroll in coverage prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment (or reenrollment) materials, and decline to provide an exemption for existing group market fixed indemnity excepted benefit coverage. HHS is similarly finalizing the individual market proposal to prominently display the notice on the first page of any marketing, application, and enrollment or reenrollment materials that are provided at or before the time an individual has the opportunity to apply, enroll or reenroll in coverage, and on the first page of the policy, certificate, or contract of insurance, and also declines to provide an exemption for existing individual market fixed indemnity excepted benefit coverage. These changes will ensure that fixed indemnity excepted benefit coverage is clearly identified as fixed indemnity coverage and not comprehensive coverage when marketed and sold in both the group and individual markets.

Some commenters opposed the adoption of a notice requirement in the group market and questioned its permissibility in the individual market. These commenters argued the Departments have no legal authority to require group health plans and issuers offering fixed indemnity excepted benefits coverage in the group market to provide such a notice. One commenter, while recognizing that the existing individual market notice was not at issue in *Central United Life Ins. Co.* v. *Burwell,* argued that requiring a notice was akin to the type of additional criterion that the D.C. Circuit found impermissible in the case.[236]

The Departments disagree with commenters that question the Departments' legal authority to adopt a consumer notice for fixed indemnity excepted benefits coverage in the group and individual markets. Through the enactment of the Federal excepted benefits statutes,[237] Congress generally preserved Federal authority to interpret and implement the statutory provisions governing these insurance products. Congress also provided the Departments with explicit authority to promulgate regulations as the Secretaries determine may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act.[238] These statutes collectively provide the Departments authority to interpret and implement the requirements for hospital indemnity or other fixed indemnity insurance to qualify as excepted benefits coverage under the Federal framework, and to adopt a consumer disclosure notice in regulation to ensure that the statutes themselves function as Congress intended. As explained in the 2023 proposed rules[239] and in section I.D. and this section III.B of the preamble of these final rules, fixed indemnity excepted benefits coverage is not an adequate substitute for comprehensive coverage, in part because it is not subject to Federal consumer protections and requirements that apply to comprehensive coverage. Consumers who purchase fixed indemnity excepted benefits coverage under the mistaken impression that such coverage is subject to Federal consumer protections and requirements for comprehensive coverage are at significant risk of financial and health hardships that may not become clear to the consumer until the occurrence of a costly health event.[240]

Consumers cannot adequately access Federal consumer protections to which they are entitled when it is unclear to which products they apply, and the effects of these protections are diluted when consumers are unclear what type of product they are purchasing and how and when they are protected by Federal law. Therefore, a consumer notice that clearly identifies a product as fixed indemnity excepted benefits coverage and distinguishes such a product from comprehensive coverage, clarifies and strengthens these protections for consumers. In addition, the notice prevents plans and issuers from marketing products that have been approved as an excepted benefit as comprehensive coverage to which Federal protections apply. Therefore, the Departments are of the view that it is necessary and appropriate for plans and issuers to provide consumers with a consumer notice that clearly labels fixed indemnity excepted benefits coverage and provides consumers with information sufficient to notify the consumer that such coverage is not subject to the Federal consumer protections and requirements for comprehensive coverage.

[236] 827 F.3d 70 (D.C. Cir. 2016).

[237] *See* section 9831 of the Code, section 732 of ERISA, and sections 2722(b)–(c), 2763, and 2791(c) of the PHS Act.

[238] *See* section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

[239] *See, for example,* 88 FR 44596 at 44619, 44620, 44645–44646 (July 12, 2023).

[240] *See id.* at 44605, 44606 (citing Appleby, Julie (2017). "Brokers Tout Mix-And-Match Coverage To Avoid High-Cost ACA Plans," KFF, available at: *https://kffhealthnews.org/news/brokers-tout-mix-and-match-coverage-to-avoid-high-cost-aca-plans*), 44608 (citing Avila, Jaie (2019). "Show Me Your Bill Helps Wipe Out $70K in Charges After Heart Attack," News 4 San Antonio, available at: *https://news4sanantonio.com/news/trouble-shooters/show-me-your-bill-helps-wipe-out-70k-in-charges-after-heart-attack*) (July 12, 2023).

The Departments also disagree with the commenter who stated requiring a notice was akin to the type of additional criterion that the D.C. Circuit found impermissible in *Central United Life Ins. Co.* v. *Burwell.* Adoption of the Federal consumer notice is not an impermissible requirement being added to the statutory criteria for fixed indemnity excepted benefits coverage. To ensure that the Code, ERISA, and the PHS Act function as intended, the notice ensures that fixed indemnity excepted benefits coverage is marketed and labeled as such, rather than as comprehensive coverage. As discussed in this section III.B.1 of this preamble, the rules do not require the provision of a notice, but instead simply provide that insurance offered without such a notice would not qualify as fixed indemnity excepted benefits coverage and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. Plans and issuers will not be prohibited from selling hospital indemnity and other fixed indemnity insurance, and consumers may continue to choose to purchase it, but unless the coverage includes the requisite notice identifying it as coverage not subject to the Federal consumer protections and requirements subject to comprehensive coverage, it would be subject to such protections and requirements. Additionally, the notice is being adopted to further the Departments' interest in ensuring that consumers are fully aware that they are purchasing fixed indemnity excepted benefits coverage rather than comprehensive coverage, are aware of their options to purchase comprehensive coverage, and have access to information resources that support informed consumer decision-making with regard to health coverage.

Further, the changes to the individual market consumer notice and the adoption of a notice in the group market are reflective and responsive to changes observed by the Departments in market conditions and the legal landscape. As discussed in section II.A of this preamble, market conditions have changed and increased the availability of affordable options for comprehensive coverage. As discussed in section II.D of this preamble, the legal landscape has also changed. The decision in *Central United Life Ins. Co.* v. *Burwell* and the passage of the Tax Cuts and Jobs Act increase the likelihood that individuals would purchase fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage. As a result of those changes, the Departments are of the view that notices will help combat deceptive marketing practices and potential sources of misinformation by clearly identifying fixed indemnity excepted benefits coverage and distinguishing such coverage from comprehensive coverage, directing consumers to appropriate resources to learn more about comprehensive coverage, and identifying key differences between that coverage and fixed indemnity excepted benefits coverage.

Many commenters stated that the proposals regarding notices in the 2023 proposed rules usurp States' authority. Several commenters pointed to the McCarran-Ferguson Act, stating that only Congress may infringe on the States' exercise of their authority to regulate insurance. Several commenters stated that Federal regulatory changes are not necessary because States and the NAIC have been working on the NAIC Models 40, 170, 171 and 880 that address these coverage options,[241] and when those are adopted by States, they will adequately address the Departments' concerns. Several commenters stated that amendments to the Federal regulations are not necessary because States have enforcement authority to discipline agents, discipline issuers, limit marketing practices, and limit product features if there are instances of fixed indemnity excepted benefits coverage being sold as a replacement for comprehensive coverage.

The Departments agree that the States play an important role in regulating fixed indemnity excepted benefits coverage and acknowledge the federalism implications of the proposed rules and these final rules.[242] As noted by commenters, the McCarran-Ferguson Act generally affirms the preeminence of State regulation, and also explicitly allows for Federal regulation when an act of Congress specifically relates to the business of insurance. As discussed in section III.A.1 of this preamble, the McCarran-Ferguson Act balances State and Federal interests in regulating the business of insurance. Section 1012(a) of the McCarran-Ferguson Act maintained State regulatory authority by enabling State preemption of some Federal law, and section 1012(b) of the McCarran-Ferguson Act limited Federal regulatory authority by generally exempting the "business of insurance" from Federal law. Although Congress allowed for State preemption of Federal law in this way, Congress also preserved Federal authority to regulate insurance provided that, to overcome the State preemption, congressional action must specifically relate to the business of insurance. As previously noted, HIPAA, the ACA, and the other Acts of Congress specifically relate to the business of insurance. Given that Congress defined and set forth criteria for fixed indemnity excepted benefits coverage to be exempt from the Federal consumer protections and requirements for comprehensive coverage,[243] there is clear congressional action specifically addressing the business of insurance, thereby preserving Federal regulatory authority to interpret and implement the Federal statutory provisions governing these insurance products.

In addition, as previously noted, Congress also provided the Secretaries of the Treasury, Labor, and HHS with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the Code, ERISA, and the PHS Act.[244] This includes the authority for the Departments to interpret and implement the requirements for hospital indemnity or other fixed indemnity insurance to qualify as excepted benefits coverage under Federal law, and also provides the authority to adopt a consumer notice. The Code, ERISA, and the PHS Act impose certain requirements on comprehensive coverage and do not impose those same requirements on fixed indemnity excepted benefits coverage. The Departments believe it is necessary and appropriate that plans and issuers provide consumers considering the purchase (or renewal) of fixed indemnity excepted benefits coverage, and those actually purchasing such insurance, a notice that clearly identifies the insurance as fixed indemnity excepted benefits coverage and is sufficient to put consumers on notice that such coverage is not subject to the Federal consumer protections and requirements for comprehensive coverage. The notices also direct consumers to resources where they can learn about the range of available coverage options, and the notices are designed to help combat the misinformation and deceptive tactics that can lead to consumers mistakenly enrolling in fixed indemnity excepted benefits coverage in lieu of comprehensive coverage. This will help ensure that consumers who purchase

[241] NAIC model laws are available at: *https://content.naic.org/model-laws.*

[242] For further discussion of the Federalism implications of these final rules, see section V.H of this preamble.

[243] *See* sections 9831 and 9832 of the Code, sections 732 and 733 of ERISA, and sections 2722, 2763, and 2791 of the PHS Act.

[244] *See* section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

fixed indemnity excepted benefits coverage are doing so based on an informed decision and not in error.

The notice provisions being finalized in these final rules do not infringe on States' authority to regulate insurance. States retain authority to regulate fixed indemnity excepted benefits coverage. States may impose standards or requirements on hospital indemnity or other fixed indemnity insurance for purposes of State law, such as a requirement to provide a State-specific notice in relation to fixed indemnity excepted benefits coverage offered by issuers in their State, including any notice developed as part of an NAIC Model Act or Regulation. However, hospital indemnity or other fixed indemnity insurance that does not include the language in the revised notice under these final rules would not be considered fixed indemnity excepted benefits coverage for purposes of Federal law and thus would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage.

The Departments are of the view that these final rules appropriately balance States' interests in regulating health insurance issuers and their health insurance markets with Congress' intent to establish a general Federal framework for health insurance coverage, including the provision of certain key protections to consumers enrolled in comprehensive coverage and the creation of an exemption for insurance products that meet the requirements to be considered excepted benefits coverage. The Departments recognize that States have been working with the NAIC to revise several model acts and regulations related to marketing and sales practices and those models might address some of the Departments' concerns. However, those models establish minimum standards and States' adoption of any NAIC model is optional. States may choose to codify some or none of the standards set forth in the NAIC models, which have yet to be finalized. The Departments will engage with States and the NAIC as they revise several NAIC Model Acts and regulations to update the minimum standards for non-comprehensive coverage products, including fixed indemnity excepted benefits coverage. The Departments look forward to reviewing the information and data collected on such products from the NAIC data call that is currently underway.

A few commenters stated that the notice provisions in the individual and group markets raised First Amendment concerns, alleging that the Departments did not articulate a compelling governmental interest because the 2023 proposed rules failed to provide any substantial evidence that consumer confusion is widespread. Those commenters further asserted that the notice provisions for the group and individual markets are not narrowly tailored, and that requiring display on the first page of marketing and enrollment materials (in addition to application materials) is not justified.

The Departments disagree that the proposed notice provisions for fixed indemnity excepted benefits coverage raise First Amendment concerns. The rules do not require the provision of a notice, but instead simply provide that hospital indemnity or other fixed indemnity insurance offered without such a notice would not qualify as fixed indemnity excepted benefits coverage and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. Moreover, as the United States Supreme Court recognized in *Zauderer* v. *Office of Disciplinary Counsel*,[245] and later reiterated in *National Institute of Family and Life Advocates* v. *Becerra*,[246] required disclosures of factual, uncontroversial information in commercial speech are subject to more deferential First Amendment scrutiny. Under the approach articulated in *Zauderer*, courts have upheld required disclosures of factual information in the realm of commercial speech where the disclosure reasonably relates to a substantial government interest and is not unjustified or unduly burdensome such that it would chill protected speech. Regardless, the Departments believe that the revised notice standard would pass muster under any form of First Amendment scrutiny.[247]

The language on the Federal notices for fixed indemnity excepted benefits coverage includes factual, uncontroversial information, reasonably relates to a government interest, and is not unjustified or unduly burdensome. In addition, the Departments have reviewed and responded to public comments that raised concerns about proposed text. For example, certain language that appeared in the proposed rules that commenters deemed controversial, such as "Warning," are not being finalized. HHS conducted consumer testing to ensure the language in the required notice was not misinterpreted to deliver any untrue messages.

The Departments have a substantial, and even compelling, government interest in ensuring consumers are aware of the type of product they are considering purchasing, are informed about key differences between fixed indemnity excepted benefits coverage and comprehensive coverage, are aware of their option to purchase comprehensive coverage, and have access to resources for additional information about the range of available health coverage options so consumers can make informed choices. As discussed in section II.B of this preamble, this is of particular importance at present due to the changing legal landscape and low health literacy, as well as the increased reports of deceptive marketing practices that play on consumer confusion about the benefits and limitations of fixed indemnity excepted benefits coverage. The notices clearly label products as fixed indemnity excepted benefits coverage and communicate factual information to consumers about the differences between fixed indemnity excepted benefits coverage and comprehensive coverage and explain how consumers can find resources when they have questions about the different coverage options. As stated in the preamble to the 2023 proposed rules, the Departments are concerned about consumers who mistakenly enroll in fixed indemnity excepted benefits coverage in lieu of comprehensive coverage and are therefore at risk of significant financial liability because their health care costs may greatly exceed the fixed cash benefit to which they may be entitled—if benefits are even provided for their health-related event.[248] Accordingly, the notices adopted in these final rules serve a legitimate government interest, are justified, and are reasonably related to these government interests.

Furthermore, these notices do not unduly burden plan or issuer speech because nothing in the final rules would "drown out" a plan's or issuer's own message or "effectively rule out" any mode of communication.[249] Plans and issuers remain free to communicate with consumers using methods and media they have always used or may choose to use in the future. The burden associated with displaying the applicable notice should be low since the Departments have adopted static language, meaning that the plan or issuer does not have to tailor or modify

[245] 471 U.S. 626 (1985).

[246] 585 U.S. 755 (2018).

[247] *See also Pharmaceutical Care Management Association* v. *Rowe*, 429 F.3d 294, 316 (1st Cir. 2005).

[248] 88 FR 44596 at 44606 (July 12, 2023).

[249] *See NIFLA*, 138 S. Ct. at 2378.

the Federal notice. For the reasons discussed previously, the Departments are of the view that informing consumers prior to purchase or reenrollment of fixed indemnity excepted benefits coverage and directing them to resources to learn more about the range of available coverage options is highly related to the government's aforementioned interest in ensuring that consumers make informed decisions.

The Departments are aware of some complex fixed indemnity policies in the individual market that pay benefits based on extensive variable schedules and other policies that promote a certain network of providers. Such plan designs mimic comprehensive coverage and can skew a consumer's understanding of the nature and extent of the fixed indemnity excepted benefits coverage. The Departments provided examples of consumer confusion regarding the limitations and exclusions associated with fixed indemnity excepted benefits coverage in the preamble to the 2023 proposed rules [250] and received additional examples from commenters. Some commenters provided examples of benefit designs that are modeled after comprehensive coverage and may cause confusion, including products requiring that enrollees meet a deductible before benefits are paid, making payments directly to providers, or using provider networks that purport to give the member a reduced or discounted medical bill for using an in-network provider. The preamble to the 2023 proposed rules also described certain arrangements in the group market that the Departments are concerned can mislead enrollees into believing they have comprehensive coverage when that is not the case.

Both the draft notice that was proposed for the group and individual markets in the 2023 proposed rules and the version being finalized in these rules are reasonably related and narrowly tailored to the government's interest in informing consumers about the limitations of fixed indemnity excepted benefits coverage, and combating deceptive marketing practices and potential sources of misinformation, by directing consumers to appropriate resources to learn more about the range of available health coverage options.[251] The notices do not include irrelevant or superfluous information unrelated to these interests.

As the Departments explained in the preamble to the 2023 proposed rules, requiring plans and issuers to display a notice on the first page of marketing, application, and enrollment materials in both markets plus on the first page of the policy, certificate, or contract of insurance in the individual market is justified to ensure that the notice is provided on documents that consumers are most likely to have the opportunity to review before application, enrollment, or reenrollment. In the Departments' view, requiring the notice only on the first page of the application is insufficient, as evidenced by ongoing consumer confusion.

The Departments proposed to require that plans and issuers prominently display the notice (in either paper or electronic form, including on a website) in at least 14-point font on the first page of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the group market fixed indemnity excepted benefit coverage. In addition, if participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of group market fixed indemnity excepted benefits coverage, the Departments proposed that the notice must be displayed in all reenrollment materials that are provided to participants at or before the time participants are given the opportunity to reenroll in coverage. The Departments explained that they consider marketing materials to include any documents or website pages that advertise the benefits or offer an opportunity to enroll (or reenroll) in group market fixed indemnity excepted benefits coverage. The Departments are finalizing the proposed requirements related to the placement of the group market consumer notice as proposed.

HHS proposed slightly different placement standards for the individual market consumer notice. The requirements reflect the differences between the types of documents that consumers typically receive when considering enrolling or reenrolling in fixed indemnity excepted benefits coverage in the individual market compared to participants in the group market. With respect to individual market fixed indemnity excepted benefits coverage, HHS proposed that issuers must also prominently display the notice (in either paper or electronic form) in at least 14-point font on the first page of the policy, certificate, or contract of insurance, including renewals or extensions, because individual market consumers are likely to receive those documents upon enrollment. This is in addition to prominently displaying the notice on the first page (in either paper or electronic form) of any marketing, application, and enrollment (or reenrollment) materials for individual market fixed indemnity excepted benefit coverage, and prominently displaying the notice on websites that advertise or offer an opportunity to enroll (or reenroll) in such coverage. HHS proposed the additional locations for display, rather than just application materials as required in the 2014 final rule, due to concern of ongoing consumer confusion. These proposals related to notice placement were intended to ensure that the notice is provided on documents that consumers are most likely to have the opportunity to review before application, enrollment, or reenrollment, based on the Departments' understanding of how consumers receive information related to group market versus individual market fixed indemnity excepted benefits coverage. HHS is finalizing the proposed requirements related to placement of the individual market consumer notice as proposed.

Many commenters supported the proposed placement of the notices in marketing, application, and enrollment and reenrollment materials, including websites and materials shared electronically. Some commenters also generally stated that the notices should be provided early and often so that consumers are not confronted with notice or warning language only after selecting a plan for purchase.

Some commenters expressed opposition to including the applicable notice with all marketing, application, and enrollment materials, suggesting such requirements are excessive and may reduce the impact of the notice. These commenters recommended the notice be provided in only the enrollment materials or using the existing individual market standard, which requires placement in the application materials only.

The Departments are finalizing the proposed standards regarding the placement and applicable materials on which the group market notice must appear without modification. HHS is similarly finalizing the proposed standards regarding the placement and applicable materials on which the revised individual market notice must appear without modification. The Departments disagree with the commenters who stated that including the notice on all of these materials is

[250] 88 FR 44596 at 44621–22 (July 12, 2023).

[251] 88 FR 44625 "[T]he Departments aim to reduce the potential for consumers to mistakenly enroll in hospital indemnity or other fixed indemnity insurance as their primary source of coverage and increase consumer understanding of the differences between fixed indemnity excepted benefits coverage and comprehensive coverage."

excessive and may reduce the impact of the notice itself. Including the notice on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment (or reenrollment) materials (as well as, in the individual market, the policy, certificate, or contract of insurance) is intended to ensure that the notice is provided on documents that consumers are most likely to have the opportunity to review before application, enrollment or reenrollment. To achieve this, as some commenters pointed out, it is important that the notice be available both early in the enrollment (or reenrollment) process and often. Therefore, it is the Departments' view that requiring the notice in several locations—rather than just the enrollment materials or only in the application—is not excessive due to the goal of maximizing consumers' opportunity to review the notice throughout their decision-making process, which is likely to increase the impact of the notice. The repetition will also help mitigate the potential for consumers to mistakenly enroll in fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage and will help combat deceptive marketing practices and potential sources of misinformation by directing consumers to appropriate resources to learn more about the range of available health coverage options.

The Departments recognize that providing notices imposes costs on plans and issuers and identified other scenarios where the benefits to consumers would be minimal and do not justify the administrative burden on plans and issuers to provide the notice. Specifically, these final rules do not require plans and issuers to provide the notice to beneficiaries, as well as participants, in the group market. In the Departments' view, requiring plans and issuers offering fixed indemnity excepted benefits coverage in the group market to provide notice to participants (rather than to both participants and any beneficiaries) appropriately balances the need to ensure that participants who are considering whether to enroll themselves and their beneficiaries in such coverage are sufficiently informed of their health coverage options with the administrative burden on plans and issuers to provide the notice.

In addition, because the group policy, certificate, or contract of insurance in the group market is often provided to the plan sponsor or the group health plan administrator, these final rules do not require that plans and issuers include the consumer notice in those documents for group market fixed indemnity excepted benefits coverage because doing so would not support the goal of ensuring that the consumers themselves receive the information so they can make an informed decision before enrolling (or reenrolling) in coverage. Similarly, in the individual market, HHS did not propose and is not finalizing a requirement for the notice to be provided to dependents of the individual enrolling in coverage. Instead, the individual market notice must be provided only to the policyholder.

The Departments proposed and are finalizing that the group market notice must be prominently displayed in at least 14-point font on the first page of any applicable marketing, application or enrollment materials.[252] Consistent with the approach outlined in the 2023 proposed rules, under these final rules, the Departments consider a notice to be prominently displayed if it is easily noticeable to a typical consumer within the context of the page (either paper or electronic) on which it is displayed (for example, using a font color that contrasts with the background of the document; ensuring the notice is not obscured by any other written or graphic content on the page; and, when displayed on a website, ensuring the notice is visible without requiring the viewer to click on a link to view the notice). HHS proposed, and is finalizing, the same prominent display requirements for the individual market notices that must appear on the first page of any applicable materials.[253]

Some commenters supported the proposal that the notices be prominently displayed on the first page of applicable materials in at least 14-point font. Another commenter suggested that instead of the 14-point font standard, the Departments should require that the notices are "easily noticeable to a typical consumer within the context of the page." One commenter recommended that when fixed indemnity excepted benefits coverage is sold as part of a bundled package, the applicable notice should be displayed on the front page of the bundled package, not just on the first page of fixed indemnity material, to help consumers see the notice instead of having it be embedded among many pages of material. One commenter stated that State regulators will often require pre-approval of any materials if the issuer adds any language to a previously approved insurance document, and that commenter requested that issuers have the flexibility to provide the required consumer notice on a separate document rather than the first page of the marketing, application, or enrollment (or reenrollment) materials.

The Departments agree with commenters who supported the prominent display of the notice on the first page of applicable materials in at least 14-point font. The Departments are of the view that this will help ensure that the notice is displayed in a location and font size that consumers are likely to see and will do so more effectively than a less subjective standard like an "easily noticeable" standard. The individual market regulations have required the prominent display of the notice in at least 14-point font and the Departments maintain that standard for simplicity and consistency.

The Departments appreciate the suggestion that when fixed indemnity excepted benefits coverage is sold as part of a bundled package, the notice should be displayed on the front page of the bundled package, not just on the first page of fixed indemnity material, to help consumers see the notice instead of having it be embedded among many pages of material. However, in some cases, placing the notice on the front of such a bundle may lead to increased consumer confusion if, for example, the consumer is unclear as to which insurance sold as part of the bundle is described in the notice. Therefore, the Departments decline to adopt a standard that requires the notice be displayed on the front page of a bundled package.

Likewise, the Departments decline to specify the manner in which materials must be presented to States for review and approval including approval of new language in a previously approved document. Issuers should work with States to determine which pages that include the notice must be submitted to the State for review and approval, the manner of submission, and how to verify that the submission is the first page of the material.

[252] As previously discussed in this section III.B.1 of this preamble, the Departments are finalizing the proposed requirements regarding the placement and materials on which the group market notice must appear without modification. As such, the group market notice must be prominently displayed on all marketing, application, and enrollment (or reenrollment) materials. The notice must also be prominently displayed on websites that advertise or offer an opportunity to enroll (or reenroll) in group market fixed indemnity excepted benefits coverage.

[253] As previously discussed in this section III.B.1 of this preamble, HHS is finalizing the proposed requirements regarding the placement and materials on which the individual market notice must appear without modification. As such, the revised individual market notice must be prominently displayed on the first page of the policy, certificate, or contract of insurance, as well as on all marketing, application, and enrollment (or reenrollment) materials. The notice must also be prominently displayed on websites that advertise or offer an opportunity to enroll (or reenroll) in individual market fixed indemnity excepted benefits coverage.

The Departments are finalizing the proposal that the group market notice must be prominently displayed in at least 14-point font on the first page of the applicable materials, and HHS is finalizing the parallel proposal for prominent display of the individual market notice on the first page of the applicable materials.

The existing notice requirement, which currently applies only in the individual market, requires that the following language be provided in application materials in at least 14-point type:

THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE. LACK OF MAJOR MEDICAL COVERAGE (OR OTHER MINIMUM ESSENTIAL COVERAGE) MAY RESULT IN AN ADDITIONAL PAYMENT WITH YOUR TAXES.

To align the notice with the changes made by the Tax Cuts and Jobs Act to section 5000A of the Code (reducing the individual shared responsibility payment to $0), and to clarify the message to consumers, the 2023 proposed rule proposed revisions to the individual market notice and solicited comments on two options for the notice. As previously discussed, the Departments also proposed to adopt a new notice provision for the group market and solicited comments on the same two options for the group market notice.

The first option (Format A) was as follows:

BILLING CODE 4830–01–P

Notice to Consumers About Fixed Indemnity Insurance

IMPORTANT: This is fixed indemnity insurance. **This isn't comprehensive health insurance** and **doesn't** have to include most Federal consumer protections for health insurance.

Visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325) to review your options for comprehensive health insurance. If you're eligible for coverage through your employer or a family member's employer, contact the employer for more information. Contact your State department of insurance if you have questions or complaints about this policy.

The second option (Format B) was as follows:

WARNING

This is not comprehensive health insurance. This is fixed indemnity insurance.

This may provide a cash benefit when you are sick or hospitalized. It is not intended to cover the cost of your care.

Contact your State department of insurance if you have questions or complaints about this policy.

For info on comprehensive health insurance coverage options:

- Visit HealthCare.gov online or call 1-800-318-2596 (TTY: 1-855-889-4325)
- Contact your employer or family member's employer

BILLING CODE 4830–01–C

One commenter stated that the general promise of a cash benefit on Format B could be read too broadly by a consumer with low health insurance literacy. Another commenter suggested that the phrase "Important Notice—Please Read Carefully" should appear at the top of the notice because that phrase would better catch the attention of consumers and inform them that this is important information that they should consider prior to making a decision. Another commenter suggested the notice should include the words "by law" before the phrase "does not have to include" most Federal consumer protections on Format A to make it clear that this coverage, by law, is not subject to the ACA or other Federal health coverage mandates. Several commenters indicated that information on the notice should be provided in a bulleted format to ensure that all factors are clearly listed. Some commenters recommended adopting Format B for greater accessibility and stated that version is written more concisely and in plain language. One commenter suggested Format B provides clarity to the reader about the nature of the insurance product by using the term "WARNING" instead of "IMPORTANT."

Other commenters opposed the use of Format B, stating that this option was misleading, confusing, and inaccurate. Several commenters suggested that the use of the term "WARNING" inappropriately implies that the coverage is inherently dangerous, noting that in other Federal labeling requirements, the use of the term "WARNING" is limited to extreme situations where the product itself is inherently unsafe. These commenters stated that hospital indemnity or other fixed indemnity insurance is not inherently hazardous or harmful, and the term "IMPORTANT" would be more appropriate and accurate. Some commenters stated that Format B included language regarding covering the cost of care, which is not entirely accurate, and that the language suggests the policy is subject to, but avoiding, Federal coverage mandates. Those commenters stated that Format B may therefore exacerbate consumer confusion.

In response to the comments on the proposed content for the notices and the different formats outlined in the 2023 proposed rules, HHS performed consumer testing to evaluate commenters' suggestions and better understand how the different formats for the notice could be interpreted by consumers. This consumer testing found that some consumers were unclear on the meaning of the phrase "cash benefit" within the context of the notice in Format B. Consumers also reported they were confused by the phrase "it is not intended to cover the cost of your care" in Format B of the proposed notice; some consumers noted that phrase only referred to their out-of-pocket costs that may be associated with the policy, such as a deductible or copay. The consumer testing also revealed that consumers prefer "IMPORTANT" and viewed "WARNING" as too strong. They stated that "IMPORTANT" was sufficient to draw their attention to the notice, and that adding the words "by law" before the phrase regarding Federal consumer protections was superfluous and not necessary.

In response to comments stating that Format B was written more concisely and in plain language, as well as the results of the consumer testing and feedback from plain language experts, the Departments are finalizing a modified version of Format B. The modified version provides information using a bulleted format to ensure all information is clearly listed, as commenters recommended.

The Departments modified Format B to address comments that claimed that format was misleading, confusing, and inaccurate. The finalized notice does not include the phrase "cash benefit" or "by law" or the word "Warning." HHS is similarly not including these same phrases in the individual market notice that is finalized in these final rules. The Departments also decline to add "Important Notice—Please Read Carefully" because consumer testing revealed that including the word "IMPORTANT" in all uppercase was sufficient to identify the applicable notice as a document that should be read. The Departments have revised the group market notice language to include "You're still responsible for paying the cost of your care" because consumers who were tested understood that terminology better than the proposed phrase "It is not intended to cover the cost of your care" included in Format B of the proposed notice. In addition to that phrase, the Departments are also adding the statement "The payment you get isn't based on the size of your medical bill" to highlight that the fixed indemnity excepted benefit is a fixed payment amount and not related to the billed amount. For the same reason, the Departments have also revised the group market notice language to state "Since this policy isn't health insurance, it doesn't have to include most [F]ederal consumer protections that apply to health insurance," rather than the proposed statement in Format B of the proposed notice that the policy "doesn't have to include most Federal consumer protections for health insurance." The revised phrasing avoids suggesting that the policy is subject to, but avoiding, the Federal consumer protections and requirements applicable to comprehensive coverage. HHS is adopting the same revisions to the language in the revised individual market consumer notice.

The Departments welcomed comments on any benefits or burdens that would be associated with including information to direct consumers to State-specific resources as part of the notice, including identifying the applicable State Exchange if the fixed indemnity excepted benefits coverage is filed in a State that does not use HealthCare.gov. The Departments also welcomed comments on any burdens that would be created by providing State-specific contact information for the State agency responsible for regulating fixed indemnity excepted benefits coverage in the State where the coverage is filed, rather than a generic reference to the consumer's State department of insurance, as proposed in both Format A and Format B. For products that are filed in multiple States, the Departments solicited comments on whether the notice should include the name and phone number for the State department of insurance of the State in which the individual to whom the fixed indemnity excepted benefits coverage is sold or marketed resides, unless the product is not filed in that State. Under this approach, if the product is not filed in the State in which the individual to whom the fixed indemnity excepted benefits coverage is sold or marketed resides, the notice would need to include the name and phone number for the department of insurance of the State in which the fixed indemnity excepted benefits coverage policy is filed.

Several commenters supported including State-specific details in the notice, including contact information for the State's Exchange and department of insurance. One commenter strongly supported including State-specific contact information in the notice, to ensure that consumers have access to the resources they need to understand their hospital indemnity and other fixed indemnity insurance policy.

Other commenters opposed customization of the notice to include State-specific resources, stating customization would increase administrative burden and cost and potentially create consumer confusion. One commenter noted that some

companies that make fixed indemnity excepted benefits products available in multiple States often use universally applicable brochures for those products, and those issuers would be required to stop longstanding, efficient marketing and enrollment processes with little benefit to consumers, who can easily obtain State-specific contact information elsewhere.

One commenter did not support the inclusion of contact information for each State department of insurance but recommended that the Departments consider directing consumers to the NAIC's online directory, available at *naic.org*. The Departments did not receive comments regarding which State agency's contact information should be included for products that are filed in multiple States.

In developing the notice language, the Departments sought to balance the goals of distinguishing fixed indemnity excepted benefits coverage from comprehensive coverage, combatting deceptive marketing practices, and reducing misinformation by directing consumers to appropriate resources to learn about the range of available coverage options, with the need to provide a concise, understandable notice that would be meaningful and useful to consumers. The Departments understand commenters' concerns regarding the burden associated with customizing notices to include State-specific information. However, the Departments also recognize the value of including State-specific information, such as appropriate contact information if the consumer has questions or wants more information about available coverage options.

After consideration of comments and the results of consumer testing, the Departments are finalizing changes to the notice to incorporate uniform language as part of the required content for the Federal notices that directs individuals to an NAIC web page where they can find the contact information for the applicable State regulatory agency. As discussed in section III.A.4 of this preamble, the inclusion of the NAIC link in the notice does not constitute an endorsement by the Departments. Since the Departments are not requiring State-specific contact information on the Federal notice, the Departments decline to specify a certain agency's contact information that should be included for products that are filed in multiple States.

The Departments are also incorporating static language as part of the content for the group market notice in these final rules that direct individuals to HealthCare.gov, where individuals can navigate to their State's Exchange, whether a Federally-facilitated Exchange, State Exchange on the Federal platform or a State Exchange. HHS is adopting similar static language for the individual market notice. This approach is intended to balance the desire to ensure individuals can access State-specific information with not increasing the burden on plans and issuers associated with the development of customized notices that provide State-specific information.

The Departments also solicited comments on whether it would be beneficial to consumers to require plans and issuers to include language on the notice that clearly informs consumers that the notice is an officially required document, such as "This notice is required by Federal law." The Departments did not receive comments regarding inclusion of that phrase on the required notice for fixed indemnity excepted benefits coverage but performed consumer testing on notices that included the phrase. Consumer testing revealed that some consumers stated that including that phrase at the bottom of the notice was helpful and that it made the information on the notice seem more legitimate, while other consumers stated the phrase meant the fixed indemnity excepted benefits policy itself was endorsed by the Federal Government. Given the potential for consumer confusion, the Departments are not including a statement that the notice is required by Federal law.

In response to comments and after consideration of the results from the consumer testing, to enhance readability, the Departments made several changes to incorporate a combination of the language from both Format A and Format B in the 2023 proposed rules and are finalizing the following content for the group market notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (**naic.org**) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

HHS is finalizing the same content for the revised individual market notice for fixed indemnity excepted benefits coverage.

Some commenters recommended requiring that the formatting of the notice be accessible to people with a range of disabilities and that it be made available in the most commonly spoken languages in each State. The Departments agree that it is important that the notices are accessible and understandable to individuals with disabilities, as well as to individuals with limited English proficiency. The Departments are mindful of the challenges faced by individuals with physical, sensory, or cognitive disabilities, including but not limited to individuals who use screen readers and other assistive technology.

While the Departments did not propose and are not finalizing accessibility or language access standards specific to these notices as part of this rulemaking, the Departments remind plans and issuers that they are required to comply with other State and Federal laws establishing accessibility and language access standards to the extent applicable. For example, recipients of Federal financial assistance must comply with Federal civil rights laws that prohibit discrimination. These laws may include section 1557 of the Affordable Care Act,[254] title VI of the Civil Rights Act of 1964,[255] section 504 of the Rehabilitation Act of 1973,[256] and the Americans with Disabilities Act of 1990.[257] Section 1557 and title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services such as written translation of written content, in paper or electronic form into languages other than English.

[254] 42 U.S.C. 18116.
[255] 42 U.S.C. 2000d *et seq.*
[256] 29 U.S.C. 794.
[257] 42 U.S.C. 12101 *et seq.*

Sections 1557 and 504 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Additionally, section 508 of the Rehabilitation Act of 1973 requires that information provided through information and communication technology also must be accessible to individuals with disabilities unless certain exceptions apply.

2. Technical Amendment

HHS proposed a technical amendment to the individual market excepted benefits rules to remove the existing requirement at 45 CFR 148.220(b)(4)(i) that fixed indemnity excepted benefits coverage must be provided only to individuals who attest, in their fixed indemnity insurance application, that they have other health coverage that is MEC, or that they are treated as having MEC due to their status as a bona fide resident of any possession of the United States pursuant to section 5000A(f)(4)(B) of the Code. This proposal would strike from the regulatory text the provision that was vacated in *Central United Life Ins. Co.* v. *Burwell*.[258] HHS did not receive any comments regarding this proposed technical amendment and is finalizing as proposed. HHS is also finalizing the proposed conforming amendments to 45 CFR 148.220 to redesignate paragraphs (b)(4)(ii) through (iv) as paragraphs (b)(4)(i) through (iii).[259]

3. Applicability Dates

The Departments proposed that the new group market notice provisions would apply to both new and existing group market fixed indemnity excepted benefits coverage for plan years beginning on or after the effective date of the final rules. HHS proposed a similar applicability date for the revised individual market fixed indemnity excepted benefits coverage notice. After consideration of comments, the Departments are finalizing delayed applicability dates for the notices, such that plans and issuers will be required to comply with the notice provisions finalized in these rules for plan years (in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025. To streamline the regulatory text, the Departments are finalizing the applicability date for the notice provision for fixed indemnity excepted benefits coverage in the group market at 26 CFR 54.9831–1(c)(4)(ii)(D), 29 CFR 2590.732(c)(4)(ii)(D), and 45 CFR 146.145(b)(4)(ii)(D) rather than at 26 CFR 54.9831–1(c)(4)(iv), 29 CFR 2590.732(c)(4)(iv), and 146.145(b)(4)(iv), as proposed. HHS is finalizing the applicability date for the notice provisions for fixed indemnity excepted benefit coverage in the individual market at 45 CFR 148.220(b)(4)(iii),[260] rather than at 148.220(b)(4)(iv).

Several commenters supported issuing updated notices to existing policyholders by applying the notice provisions finalized in these rules to coverage periods (including renewals) beginning on or after January 1, 2025. Other commenters stated the notice provisions should not apply before January 1, 2027, for all individual and group coverage, regardless of when the coverage is issued or sold. Some commenters urged the Departments to apply the notice provisions only to new coverage sold after the effective date of the final rules, alleging that the application to existing coverage would be impermissibly retroactive. Those commenters stated that applying the notice to existing policies would inappropriately interfere with a covered individual's current contract and their choice to continue the policy. Some commenters asserted that imposing the notice provision on existing policies would be confusing and impractical. Another commenter recommended the applicability date for the notice provision for new coverage should be at least 24 months after publication of the final rules, to allow issuers time to update and refile products and marketing materials to reflect the necessary changes and provide State regulators with the time necessary to review and approve products and updated marketing materials. The commenters stated that it would be extremely difficult or impossible for issuers of group market coverage to make the required changes for notices to all marketing and enrollment materials for hospital indemnity and other fixed indemnity products before the effective date of these final rules. One commenter stated that it would be impossible for issuers of individual market coverage to comply with the proposed applicability dates because of the length of time necessary to obtain State-level approval for revised individual insurance contracts.

The Departments decline to extend the applicability date to January 1, 2027, as suggested by some commenters. In the Departments' view the benefits of providing the notice to consumers at an earlier time outweighs the burden on plans and issuers to incorporate the notice by the delayed applicability date for plan years (in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025. To minimize the burden, the Departments are finalizing notices that cannot be modified or customized; therefore, plans and issuers will not have to spend time or resources to develop their own notices to comply with the Federal notice standard. Plans and issuers may need to modify their website or other marketing materials to comply with the Federal notice standard and may need to submit materials for State review, but the Departments do not agree with commenters that those modifications require 24 months or more.

The Departments also disagree with commenters who stated that applying the notice to existing policies would inappropriately interfere with a covered individual's current contract. The notice does not change the terms of the contract to which the issuer and policyholder agreed. The notice will be provided to a currently covered individual at the time of renewal; therefore, there is no interference with a current contract, and the notice does not prevent an individual from renewing or reenrolling in fixed indemnity excepted benefits coverage. The Departments therefore disagree that the application of the notice provisions to existing enrollees at the time of renewal or reenrollment is impermissibly retroactive because it applies to future coverage periods and does not take away or impair vested rights or create new obligations or duties with respect to past transactions. The Departments also disagree that applying the notice provisions to existing policies would be confusing and impractical. The Departments are of the view that consumers should have information about the range of available

[258] 827 F.3d 70 (D.C. Cir. 2016).

[259] These provisions are being redesignated without any changes to the regulatory text.

[260] Under 45 CFR 148.220(b)(4)(iii)(B) of these final rules, the notice in § 148.220(b)(4)(iv) contained in 45 CFR part 148, revised as of October 1, 2023, continues to apply to individual market fixed indemnity excepted benefits coverage for coverage periods beginning before January 1, 2025. However, HHS will not consider insurance to fail to be fixed indemnity excepted benefits coverage in the individual market under the Federal framework if an issuer adopts the revised notice in these final rules for coverage periods beginning before January 1, 2025. HHS encourages States to adopt a similar approach if their issuers elect to adopt the revised notice for coverage periods that begin before January 1, 2025.

coverage options and have an opportunity to reconsider their coverage options. The notice standard under these final rules allows consumer to make an informed decision whether to maintain their existing fixed indemnity excepted benefits coverage and whether to also pursue or maintain comprehensive coverage.

The Departments are not persuaded by comments suggesting it would be extremely difficult or impossible for plans and issuers to make changes to incorporate the applicable notice in all applicable materials for hospital indemnity and other fixed indemnity products before the proposed applicability date, which was the effective date of these final rules. Nevertheless, after consideration of the comments requesting additional time to modify marketing materials and plan documents, the Departments are finalizing an applicability date for the notices adopted under these final rules to apply in the group and individual markets of plan years (in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025.[261]

The Departments proposed that the severability provisions described in section IV of this preamble would apply to both new and existing group market fixed indemnity excepted benefits coverage beginning on the effective date of these final rules. HHS proposed that the technical amendment described in section III.B.2 of this preamble and the severability provisions described in section IV of this preamble would apply to both new and existing individual market fixed indemnity excepted benefits coverage on the effective date of these final rules. HHS is only finalizing the technical amendment to remove the language in existing 45 CFR 148.220(b)(4)(i) and make conforming amendments to redesignate paragraphs (b)(4)(ii) through (iv) as paragraphs (b)(4)(i) through (iii).

HHS did not receive comments related to the applicability date for the technical amendments it is finalizing in these final rules or severability provision in the individual market regulations and is finalizing them as proposed. The Departments are also finalizing as proposed the applicability date for the group market severability provisions.

[261] HHS reminds issuers that the existing individual market notice for fixed indemnity excepted benefits coverage, codified in 45 CFR 148.220(b)(4)(iv), revised as of October 1, 2023, continues to apply for coverage periods beginning before January 1, 2025. However, HHS will not consider insurance to fail to be fixed indemnity excepted benefits coverage in the individual market under the Federal framework if an issuer adopts the revised notice in these final rules for coverage periods beginning before January 1, 2025. HHS encourages States to adopt a similar approach if their issuers elect to adopt the revised notice for coverage periods that begin before January 1, 2025.

IV. Severability

The Departments are finalizing amendments to the Federal definition of "short-term, limited-duration insurance" and certain regulatory provisions regarding the requirements for hospital indemnity and other fixed indemnity insurance to qualify as an excepted benefit in the group or individual market, for the purpose of distinguishing STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage. The Departments' authority to finalize and adopt these amendments is well-established in law and practice and should be upheld in any legal challenge. However, in the event that any portion of these final rules is declared invalid, the Departments intend that the other provisions, which could still function sensibly, would be severable.

Specifically, if any provision finalized in these final rules related to STLDI is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be considered severable from its section and other sections of these rules; and it shall not affect the remainder thereof or the application of the provision to other entities not similarly situated or to dissimilar conditions. Thus, if a court were to find the portion of the STLDI definition that limits stacking, the portion of the STLDI definition that establishes a Federal consumer notice, or any other aspect of the revised Federal STLDI definition to be unlawful, the Departments intend the remaining aspects of these final rules related to STLDI to stand.

Similarly, if any finalized provision in this rulemaking related to group or individual market fixed indemnity excepted benefits coverage is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be considered severable from its section and other sections of these rules; and such invalidation shall not affect the remainder thereof or the application of the provision to other entities not similarly situated or to dissimilar conditions.

The Departments also intend for the STLDI amendments in this rulemaking to be severable from the fixed indemnity excepted benefits coverage amendments, and vice versa.

The Departments did not receive any comments on the proposed group market severability provisions and are finalizing the proposed severability provisions as proposed. HHS also did not receive any comments on the proposed individual market severability provision and is finalizing that provision as proposed.

V. Regulatory Impact Analysis

A. Summary—Departments of Health and Human Services and Labor

These final rules revise the Federal definition of STLDI for new policies, certificates, or contracts of insurance sold or issued on or after September 1, 2024, to provide that the coverage must have an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date. These final rules also revise the Federal definition of STLDI so that the maximum total coverage duration, taking into account any renewals or extensions, is no longer than 4 months. For purposes of this definition, a renewal or extension includes the term of a new STLDI policy, certificate, or contract of insurance issued by the same issuer or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance.

For new STLDI—meaning policies, certificates, or contracts of STLDI sold or issued on or after September 1, 2024—the amendments to the definition of STLDI addressing maximum term and duration in these final rules apply for coverage periods beginning on or after September 1, 2024. Under these final rules, existing STLDI—meaning policies, certificates, or contracts of STLDI sold or issued before September 1, 2024 (including any subsequent renewals or extensions consistent with applicable law)—may continue to have an initial contract term of less than 12 months and a maximum duration of up to 36 months (taking into account any renewals or extensions), subject to any limits under applicable State law.

These final rules further revise the Federal definition of STLDI to provide that a revised notice must be prominently displayed (in either paper or electronic form) in at least 14-point font on the first page of the policy, certificate, or contract of insurance and in any marketing, application, and enrollment materials, including for renewals or extensions (including on websites that advertise or enroll

individuals in STLDI). These notice provisions apply for both new and existing STLDI for coverage periods beginning on or after September 1, 2024.

Additionally, these final rules amend the regulations regarding fixed indemnity excepted benefits coverage in the individual market to provide that a revised notice must be prominently displayed (in either paper or electronic form) on the first page of the policy, certificate, or contract of insurance, and any marketing, application, and enrollment (or reenrollment) materials that are provided at or before the time an individual has the opportunity to apply, enroll, or reenroll in coverage. These final rules also amend the regulations regarding fixed indemnity excepted benefits coverage in the group market to provide that a notice must be prominently displayed (in either paper or electronic form) on the first page of any marketing, application, and enrollment (or reenrollment) materials that are provided to participants at or before the time participants are given the opportunity to enroll (or reenroll) in the coverage. These notice provisions for group and individual market fixed indemnity excepted benefits coverage are applicable to both new and existing coverage with respect to plan years (in the individual market, coverage periods) beginning on or after January 1, 2025.

The Departments are finalizing the proposed severability provisions and HHS is also finalizing technical and conforming amendments to the individual market regulation regarding fixed indemnity excepted benefits coverage, which are not expected to have a material impact.

The Departments have examined the effects of these final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993),[262] Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011),[263] Executive Order 14094 (April 6, 2023),[264] the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999),[265] and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866, 13563, and 14094—Departments of Health and Human Services and Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled "Modernizing Regulatory Review" amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) for changes in gross domestic product), or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, Territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866, as specifically authorized in a timely manner by the Administrator of OIRA in each case.[266]

A regulatory impact analysis (RIA) must be prepared for significant rules. Based on the Departments' estimates, OMB's OIRA has determined this rulemaking is significant under section 3(f)(1) as measured by the $200 million threshold in any 1 year. Therefore, OMB has reviewed these rules, and the Departments have provided the following assessment of their impact. With respect to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act, OMB's OIRA has also determined that these rules fall within the definition provided by 5 U.S.C. 804(2).

1. Need for Regulatory Action

The 2018 final rules permit enrollment in an STLDI policy with a total duration that could extend up to 36 months (including renewals or extensions). This insurance might therefore be viewed as (and, in some cases, has been deceptively marketed as) a substitute for comprehensive coverage, rather than as a way to bridge a temporary gap in comprehensive coverage.[267] Evidence shows that the number of consumers buying STLDI increased following the effective date of the 2018 final rules. Data from the NAIC indicate that the number of individuals covered by STLDI in the individual market more than doubled between 2018 and 2019, from approximately 87,000 to 188,000, and further increased to approximately 238,000 in 2020, before declining to approximately 173,000 in 2021 following the expansion of PTC subsidies provided through the ARP.[268] The number of individuals covered by STLDI sold to individuals (not enrolled as members of an association) rose once again in 2022, however, to approximately 236,000.[269] While these figures do not capture the total number of individuals covered by STLDI throughout each year (rather, only at the end of the calendar year), and do not include individuals covered by STLDI sold to or through associations, they do show the trend of increased enrollment in STLDI following the implementation of the 2018 final rules. Projections by the Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT) suggest that 1.5 million people could

[262] Executive Order 12866 of September 30, 1993, 58 FR 51735 (October 4, 1993).

[263] Executive Order 13563 of January 18, 2011, 76 FR 3821 (January 21, 2011).

[264] Executive Order 14094 of April 6, 2023, 88 FR 21879 (April 11, 2023).

[265] Executive Order 13132 of August 4, 1999, 64 FR 43255 (August 10, 1999).

[266] Executive Order 14094 of April 6, 2023, 88 FR 21879 at 21879 (April 11, 2023).

[267] For one example of deceptive marketing practices, *see* Federal Trade Commission (2022). "FTC Action Against Benefytt Results in $100 Million in Refunds for Consumers Tricked into Sham Health Plans and Charged Exorbitant Junk Fees," available at: *https://www.ftc.gov/news-events/news/press-releases/2022/08/ftc-action-against-benefytt-results-100-million-refunds-consumers-tricked-sham-health-plans-charged.*

[268] National Association of Insurance Commissioners (2022). Accident and Health Policy Experience Reports for 2018–2021, available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/SimpleSearch.*

[269] National Association of Insurance Commissioners (2023). "2022 Accident and Health Policy Experience Report," available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

currently be enrolled in STLDI,[270] and CMS previously estimated that 1.9 million individuals would enroll in STLDI by 2023.[271] However, as noted in section V.B.2.b of this preamble, these projections were developed prior to the expansion of PTC subsidies provided through the ARP and the IRA.

Given that STLDI generally is not subject to the Federal consumer protections and requirements for comprehensive coverage applicable to individual health insurance coverage, STLDI policies tend to offer limited benefit coverage and have relatively low actuarial values.[272] These plans therefore expose enrollees to the risk of high out-of-pocket health expenses and medical debt.[273]

In recent years, fixed indemnity insurance is increasingly being designed to resemble comprehensive coverage, and consumers might therefore mistakenly view it as a substitute for comprehensive coverage rather than as an insurance policy that provides independent, noncoordinated income replacement benefits that is distinct from comprehensive coverage.[274]

In addition, because STLDI and fixed indemnity insurance are sold outside of the Exchanges and are generally not subject to the Federal consumer protections and requirements for comprehensive coverage, consumers may have limited information about the limitations, value, and quality of the coverage being sold.[275] Recent evidence of consumer confusion and improper marketing regarding STLDI[276] and fixed indemnity insurance[277] support the need to improve consumer understanding of these types of insurance (and their coverage limitations) compared to comprehensive coverage. The provisions finalized in these final rules will help ensure that consumers can better understand and properly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage, and access resources to learn more about their health coverage options.

These final rules will encourage enrollment in comprehensive coverage and lower the risk that STLDI and fixed indemnity excepted benefits coverage are viewed or marketed as a substitute for comprehensive coverage.[278]

2. Summary of Impacts

The expected benefits, costs, and transfers associated with these final rules are summarized in Table 1 and discussed in detail later in this section V.B.2 of this preamble.

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[270] Congressional Budget Office (2020). "CBO's Estimates of Enrollment in Short-Term, Limited-Duration Insurance," available at: *https://www.cbo.gov/publication/56622*. CBO and JCT projected that enrollment in STLDI would reach 1.6 million by 2028. *See* Congressional Budget Office (2019). "How CBO and JCT Analyzed Coverage Effects of New Rules for Association Health Plans and Short-Term Plans," available at: *https://www.cbo.gov/publication/54915*.

[271] CMS Office of the Actuary (2018). "Estimated Financial Effects of the Short-Term, Limited-Duration Policy Proposed Rule," available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/STLD20180406.pdf*.

[272] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market*.

[273] *See, for example,* Deam, Jenny (2021). "He Bought Health Insurance for Emergencies. Then He Fell Into a $33,601 Trap," ProPublica, available at: *https://www.propublica.org/article/junk-insurance.*

[274] *See, for example,* Young, Christen Linke and Kathleen Hannick (2020). "Fixed Indemnity Health Coverage Is a Problematic Form of 'Junk Insurance,'" USC-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance*.

[275] *See* Williams, Jackson (2022). "Addressing Low-Value Insurance Products With Improved Consumer Information: The Case of Ancillary Health Products," National Association of Insurance Commissioners, *Journal of Insurance Regulation*, available at: *https://content.naic.org/sites/default/files/cipr-jir-2022-9.pdf*.

[276] *See, for example,* Deam, Jenny (2021). "He Bought Health Insurance for Emergencies. Then He Fell Into a $33,601 Trap," ProPublica, available at: *https://www.propublica.org/article/junk-insurance. See also* Palanker, Dania and Kevin Lucia (2021). "Limited Plans with Minimal Coverage Are Being Sold as Primary Coverage, Leaving Consumers at Risk," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2021/limited-plans-minimal-coverage-are-being-sold-primary-coverage-leaving-consumers-risk. See also* Schwab, Rachel and Maanasa Kona (2018). "State Insurance Department Consumer Alerts on Short-Term Plans Come Up Short," Center on Health Insurance Reforms, available at: *https://chirblog.org/state-insurance-department-consumer-alerts-short-term-plans-come-short/. See also* Corlette, Sabrina, Kevin Lucia, Dania Palanker, and Olivia Hoppe (2019). "The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses," Urban Institute, available at: *https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses*.

[277] *See, for example,* Young, Christen Linke and Kathleen Hannick (2020). "Fixed Indemnity Health Coverage Is a Problematic Form of "Junk Insurance," USC-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance. See also* Government Accountability Office (2020). "Private Health Coverage: Results of Covert Testing for Selected Offerings," available at: *https://www.gao.gov/products/gao-20-634r*.

[278] As discussed in section I.B of this preamble, these final rules build on Executive Order 14009, "Strengthening Medicaid and the Affordable Care Act," and Executive Order 14070, "Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage," by encouraging enrollment in high-quality, comprehensive coverage. The Departments also note that the affordability of comprehensive coverage offered in the individual market has increased for many consumers in recent years, due in part to the expanded PTC subsidies provided through the ARP and the IRA, as discussed in section II of this preamble. Further, as discussed in section II of this preamble, the COVID–19 PHE has highlighted the importance of encouraging enrollment in comprehensive coverage.

TABLE 1: Accounting Table

Benefits:				
Non-Quantified: • Reductions in information asymmetries in health insurance markets through increased consumer understanding of STLDI and fixed indemnity excepted benefits coverage in relation to comprehensive coverage. • Increased enrollment in comprehensive coverage, with an estimated increase in enrollment in individual health insurance coverage purchased on an Exchange by approximately 60,000 people in 2026, 2027 and 2028 associated with the provisions regarding STLDI. • Improvement in market stability and market risk pools for comprehensive coverage. • Reduction in the risk of high out-of-pocket health expenses, lower incidence of medical debt, improved health outcomes, and increased health equity, for individuals who switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage. • Potential reduction in the overall number of STLDI coverage rescissions or claims denials, if enrollment in STLDI declines. • Potential reduction in deceptive or aggressive marketing practices and harm from such practices involving the sale of STLDI and fixed indemnity excepted benefits coverage.				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$111,140	2024	7 percent	2024-2028
	$103,367	2024	3 percent	2024-2028
Quantified: • One-time regulatory review costs of approximately $358,578 for issuers of STLDI, issuers of fixed indemnity excepted benefits coverage, and other interested parties. • One-time costs of approximately $129,015 for issuers of STLDI and fixed indemnity excepted benefit coverage associated with complying with the notice provisions.				
Non-Quantified: • Potential increase in premium costs for individuals who switch from STLDI or fixed indemnity excepted benefit coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and who are not eligible for the PTC. • Potential increase in the number of uninsured individuals or the number of individuals experiencing a coverage gap, if some individuals with STLDI coverage purchased after the applicability date are no longer able to renew or extend their current policy, choose not to purchase a new policy from another issuer of STLDI, and can only obtain comprehensive coverage during open enrollment, or choose not to purchase comprehensive coverage. • Potential decrease in compensation for agents and brokers if there is a reduction in sales of STLDI and fixed indemnity excepted benefits coverage. • Potential increase in health care spending, if individuals switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and increase their use of health care as a result. • Potential costs to States, if States enact or implement new legislation in response to these final rules. • Potential costs to State departments of insurance associated with reviewing amended marketing materials and plan documents filed by issuers of STLDI and fixed indemnity excepted benefits coverage in response to these final rules.				
Transfers:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	- $67.1 million	2024	7 percent	2024-2028
	- $69.9 million	2024	3 percent	2024-2028
Quantified: • Reduction in gross premiums for individuals enrolled in individual health insurance coverage purchased on an Exchange by approximately 0.5 percent in 2026, 2027, and 2028. • Decrease in Federal PTC spending of approximately $120 million in 2026, 2027, and 2028.				
Non-Quantified: • Potential transfer from issuers to consumers if consumers switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage and experience a reduction in out-of-pocket costs.				

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Table 2 presents the estimated effects of the provisions regarding STLDI on enrollment in and gross premiums for individual health insurance coverage

purchased on an Exchange, and on Federal spending on the PTC (by calendar year), as discussed further in sections V.B.2.c and V.B.2.e of this preamble. The Departments estimate that, starting in 2026, total enrollment in individual health insurance coverage purchased on an Exchange will be higher by 60,000 individuals each year, premiums for this coverage will be lower by 0.5 percent each year, and Federal spending on the PTC will be lower by $120 million each year, relative to the current status quo. The cumulative reduction in Federal spending on the PTC will be (an undiscounted) $360 million from 2026 to 2028.

TABLE 2: Estimated Effects of the Provisions Regarding STLDI on Enrollment in and Gross Premiums for Individual Health Insurance Coverage Purchased on an Exchange and on Federal Spending on the PTC

Calendar Year	2024	2025	2026	2027	2028
Change in Enrollment in Individual Health Insurance Coverage Purchased on an Exchange	0	0	60,000	60,000	60,000
Percentage Change in Gross Premiums for Individual Health Insurance Coverage Purchased on an Exchange	0	0	-0.5	-0.5	-0.5
Change in Federal Spending on the PTC (in millions)	$0	$0	-$120	-$120	-$120

a. Background

STLDI and fixed indemnity excepted benefits coverage generally are not subject to the Federal consumer protections and requirements for comprehensive coverage, as discussed in more detail in section I.A of this preamble. When used as a long-term substitute for comprehensive coverage, STLDI and fixed indemnity insurance expose enrollees to financial and health risks, as discussed in this section and section II.B of this preamble.

STLDI and fixed indemnity insurance typically do not cover all essential health benefits (including, for example, prescription drugs, maternity services, and mental health and substance use disorder services), and typically do not cover preexisting conditions.[279] STLDI may offer fewer benefits overall.[280] Fixed indemnity insurance is designed to provide a source of income replacement or financial support following a qualifying health-related event, and benefits are often far below a covered individual's incurred costs related to a medical event.[281] STLDI and fixed indemnity insurance typically have lower loss ratios or actuarial values than coverage subject to the Federal consumer protections and requirements for comprehensive coverage. In one study of the medical claims of approximately 47 million enrollees in commercial plans in 2016, for example, the implied actuarial value of the STLDI coverage in the study was 49 percent, compared to an implied actuarial value of approximately 74 percent for off-Exchange comprehensive coverage plans and an implied actuarial value of 87 percent for on-Exchange plans.[282] Additionally, according to an NAIC report, across 28 issuers of STLDI in the individual market in 2021, the nationwide loss ratio was approximately 70 percent.[283] The same report stated that across 95 issuers of "other medical (non-comprehensive)" coverage in the individual market, which includes fixed indemnity insurance, the nationwide loss ratio was approximately 40 percent in 2021.[284] By contrast, according to data from medical loss ratio (MLR) annual reports for the 2021 MLR reporting year, the average MLR in the individual market for comprehensive coverage was approximately 87 percent in 2021.[285]

A few commenters also noted that STLDI and fixed indemnity insurance

[279] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market. See also* Pollitz, Karen, Michelle Long, Ashley Semanskee, and Rabah Kamal (2018). "Understanding Short-Term Limited Duration Health Insurance," KFF, available at: *https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/. See also* Sanger-Katz, Margot (2018). "What to Know Before You Buy Short-Term Health Insurance," *The New York Times,* available at: *https://www.nytimes.com/2018/08/01/upshot/buying-short-term-health-insurance-what-to-know.html. See also* Partnership to Protect Coverage (2021). "Under-Covered: How 'Insurance-Like' Products are Leaving Patients Exposed," available at: *https://www.nami.org/NAMI/media/NAMI-Media/Public%20Policy/Undercovered_Report_03252021.pdf. See also* Young, Christen Linke and Kathleen Hannick (2020). "Fixed Indemnity Health Coverage Is a Problematic Form of "Junk Insurance" USC-Brookings Schaeffer Initiative for Health Policy, available at: *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/08/04/fixed-indemnity-health-coverage-is-a-problematic-form-of-junk-insurance.*

[280] *See, for example,* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[281] *See* Williams, Jackson (2022). "Addressing Low-Value Insurance Products With Improved Consumer Information: The Case of Ancillary Health Products," National Association of Insurance Commissioners, *Journal of Insurance Regulation,* available at: *https://content.naic.org/sites/default/files/cipr-jir-2022-9.pdf.*

[282] Pelech, Daria and Karen Stockley (2022). "How Price and Quantity Factors Drive Spending in Nongroup and Employer Health Plans," Health Services Research, available at: *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13962.*

[283] The loss ratio is calculated as ((Incurred Claims Amount + Change in Contract Reserves)/Premiums Earned). Data regarding issuers of STLDI and "other non-comprehensive coverage" are only available for the individual market. *See* National Association of Insurance Commissioners (2022). "2021 Accident and Health Policy Experience Report," available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/AdvancedSearch.*

[284] National Association of Insurance Commissioners (2022). "2021 Accident and Health Policy Experience Report," available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/AdvancedSearch.* Data regarding issuers of non-comprehensive coverage are only available for the individual market.

[285] Based on internal calculations. Source: CMS, Medical Loss Ratio Data and System Resources, available at: *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

have low average loss ratios as compared to comprehensive coverage. These comments and the previously-mentioned statistics suggest that relative to issuers of comprehensive coverage, issuers of STLDI tend to spend a lower percentage of premium dollars on health care items and services, and issuers of fixed indemnity insurance tend to spend a lower percentage of premium dollars on payment of benefits. STLDI and fixed indemnity insurance can therefore be highly profitable for issuers,[286] depending on the extent to which issuers incur costs related to marketing (including agent/broker compensation [287]), policy underwriting, and overhead.

Low average loss ratios for STLDI and fixed indemnity insurance, along with relatively high commission rates for agents and brokers of those policies, reduce the value of STLDI and fixed indemnity insurance for consumers. Agents and brokers act as intermediaries between consumers and issuers. Their income is primarily derived from commissions, which tend to be a percentage of premiums paid by the consumer to the issuer. The commissions are incorporated into the cost of an insurance plan, and therefore indirectly affect the total price paid by the consumer for the coverage purchased. There is limited data available on commission rates paid by issuers to agents and brokers. Agent and broker commission rates tend to vary significantly between health insurance coverage options, though issuers of STLDI and fixed indemnity insurance tend to pay higher commissions.[288] The Departments received several comments indicating that agents and brokers receive a higher percentage of the plan's premium as a commission for selling STLDI or fixed indemnity insurance as compared to individual health insurance coverage. This was also confirmed in the Departments' review of some broker compensation disclosures.[289] The Departments acknowledge that lower cost alternatives to comprehensive coverage may not result in higher total compensation for agents and brokers, since the premiums for comprehensive coverage might be higher than the premiums for STLDI and fixed indemnity insurance. However, higher commission rates for agents and brokers from sales of STLDI and fixed indemnity insurance can incentivize aggressive and/or deceptive marketing tactics that may mislead customers into enrolling in STLDI or fixed indemnity insurance instead of comprehensive coverage.[290] [291] [292] One study suggests that commissions for STLDI are up to 10 times higher than those obtained for enrollment in individual health insurance coverage (averaging approximately 23 percent of premiums for STLDI, compared to 2 percent of premiums for individual health insurance coverage).[293] Another source corroborates this finding by noting that issuers of STLDI pay commissions close to 20 percent of premiums.[294]

In the 2023 proposed rules, the Departments stated that the limited coverage provided through most STLDI and fixed indemnity excepted benefits coverage exposes individuals enrolled in these policies to health and financial risks, including the risk of high medical bills and high out-of-pocket expenses. The Departments further noted that these high out-of-pocket expenses, in turn, could contribute to an increased risk of medical debt and bankruptcy, which is particularly problematic given the extent of medical debt already present in the United States.[295] As discussed in section II.B of this preamble, commenters provided the Departments with examples of how enrollment in fixed indemnity insurance, when used as a substitute for comprehensive coverage, could expose individuals to financial risk. However, many commenters also noted that fixed indemnity insurance can reduce financial risk for individuals, given that it provides payments for unexpected expenses associated with a health-related event. The Departments acknowledge that fixed indemnity insurance can reduce financial risk when used as a supplement to comprehensive coverage but remain concerned about the financial risk for individuals when it is used as a substitute for comprehensive coverage.

Misleading marketing of STLDI and fixed indemnity insurance is reported to have taken place during annual individual market open enrollment and special enrollment periods (including during the 2021 COVID–19 special enrollment period, when Exchanges using the Federal platform made available a 6-month special enrollment period on *HealthCare.gov* to allow qualified individuals to enroll in individual health insurance coverage during the COVID–19 PHE).[296] For

[286] *See* Appleby, Julie (2018). "Short-Term Health Plans Boost Profits For Brokers And Insurers," NPR, available at: *https://www.npr.org/sections/health-shots/2018/12/21/678605152/short-term-health-plans-boost-profits-for-brokers-and-insurers*. *See* also Pear, Robert (2018). " 'Short Term' Health Insurance? Up to 3 Years Under New Trump Policy," *The New York Times*, available at: *https://www.nytimes.com/2018/08/01/us/politics/trump-short-term-health-insurance.html*.

[287] Compensation includes commissions, fees, or other incentives (for example, rewards or bonuses) as established in the relevant contract between an issuer and the agent or broker.

[288] *See* Lucia, Kevin, Sabrina Corlette, Dania Palanker, and Olivia Hoppe (2018). "Views From the Market: Insurance Brokers' Perspectives on Changes to Individual Health Insurance," Urban Institute, available at: *https://www.urban.org/research/publication/views-market-insurance-brokers-perspectives-changes-individual-health-insurance*.

[289] The Departments reviewed information detailing broker compensation from an agent/broker, two large issuers, and a health insurance agency.

[290] *See, for example.*, Appleby, Julie (2018). "Short-Term Health Plans Boost Profits For Brokers And Insurers," NPR, available at: *https://www.npr.org/sections/health-shots/2018/12/21/678605152/short-term-health-plans-boost-profits-for-brokers-and-insurers*.

[291] Government Accountability Office (2020). "Private Health Coverage: Results of Covert Testing for Selected Offerings," available at: *https://www.gao.gov/products/gao-20-634r*.

[292] However, even as some issuers offer higher compensation for STLDI, many brokers continue to refuse to sell products they view as overly risky for consumers, like STLDI. *See, for example*, Corlette, Sabrina, Erik Wengle, Ian Hill, and Olivia Hoppe (2020). "Perspective from Brokers: The Individual Market Stabilizes While Short-Term and Other Alternative Products Pose Risks," Urban Institute, available at: *https://www.urban.org/research/publication/perspective-brokers-individual-market-stabilizes-while-short-term-and-other-alternative-products-pose-risks*.

[293] U.S. House of Representatives Committee on Energy and Commerce (2020). "Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk," available at: *https://democrats-energycommerce.house.gov/newsroom/press-releases/ec-investigation-finds-millions-of-americans-enrolled-in-junk-health*.

[294] Sanger-Katz, Margot (2018). "What to Know Before You Buy Short-Term Health Insurance," *The New York Times*, available at: *https://www.nytimes.com/2018/08/01/upshot/buying-short-term-health-insurance-what-to-know.html*.

[295] *See, for example*, Consumer Financial Protection Bureau (2022). "Medical Debt Burden in the United States," available at: *https://files.consumerfinance.gov/f/documents/cfpb_medical-debt-burden-in-the-united-states_report_2022-03.pdf*.

[296] *See* Palanker, Dania and JoAnn Volk. (2021). "Misleading Marketing of Non-ACA Health Plans Continued During COVID–19 Special Enrollment Period," Center on Health Insurance Reforms, available at: *https://georgetown.app.box.com/s/mn7kgnhibn4kapb46tqmv6i7putry9gt*. *See* also Corlette, Sabrina, Kevin Lucia, Dania Palanker, and Olivia Hoppe (2019). "The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses," Urban Institute, available at: *https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses*. Regarding the establishment of the COVID–19 special enrollment period, *see* E.O. 14009; *see* also CMS (2021). "2021 Special Enrollment Period in Response to the COVID–19 Emergency," available at: *https://www.cms.gov/newsroom/fact-sheets/2021-special-enrollment-period-response-covid-19-emergency*. Regarding the extension of the COVID–19 special enrollment period (to the 6-month period between February 15, 2021, and August 15, 2021), *see* CMS (2021). "Extended Access Opportunity to Enroll in More Affordable Coverage Through *HealthCare.gov*," available at: *https://www.cms.gov/newsroom/fact-*

example, one study showed that enrollment in STLDI policies through brokers increased by approximately 60 percent in December 2018 and by more than 120 percent in January 2019, suggesting that overall enrollment in STLDI spiked during the annual individual market open enrollment period.[297] One survey suggests that lead-generating websites direct consumers to insurance brokers selling both STLDI and other types of non-comprehensive coverage, including fixed indemnity insurance, and that these types of coverage are often marketed to resemble comprehensive coverage.[298]

A number of States and the District of Columbia enacted legislation or issued regulations regarding STLDI after the 2018 final rules were published. State regulatory actions regarding STLDI have been wide-ranging. For example, according to one report, as of September 2023, four States prohibited STLDI, seven States and the District of Columbia limited the total duration of enrollment in STLDI (including renewals or extensions) to less than 3 months, and eight States have limited the initial contract terms for enrollment in STLDI to less than 6 months.[299] Other State regulatory actions on STLDI have included banning coverage rescissions (except in cases of fraud on the part of the enrollee), adding preexisting condition protections, and requiring a certain MLR, among other restrictions.[300] Lastly, some States have largely aligned their regulations regarding STLDI with the 2018 final rules.[301] In some States that allow sales of STLDI, but have additional consumer protections in place (for example, prohibitions on renewals of STLDI coverage), issuers do not offer STLDI.[302]

Recent analysis has found that States that allow the initial contract term of STLDI to last up to 364 days have seen a 27 percent reduction in enrollment, on average, in non-Exchange plans that are subject to the Federal consumer protections and requirements for comprehensive coverage from 2018 to 2020, compared with a 4 percent reduction in enrollment, on average, in those plans in States that banned STLDI or limited its duration to 6 months or less.[303] This analysis also found that market-wide risk scores (a measure of relative expected health care costs for a population) declined more in States that banned or limited STLDI (-11.8 percent) than in States with less restrictions on STLDI (-8.3 percent), suggesting that the less restrictive States saw more healthier individuals enroll in STLDI policies in lieu of comprehensive coverage, which put upward pressure on the average expected health care costs among those with comprehensive coverage.

b. Number of Affected Entities

The provisions in these final rules will affect consumers enrolled in STLDI or fixed indemnity excepted benefits coverage, issuers of STLDI, issuers offering fixed indemnity excepted benefits coverage, and agents and brokers selling STLDI or fixed indemnity excepted benefits coverage. The provisions in these rules will also affect States if they enact or implement new legislation in response to these final rules. State departments of insurance will also be impacted to the extent they need to review amended marketing materials and plan documents filed by issuers.

With respect to consumers, individuals who are currently enrolled in STLDI or who may consider purchasing or choose to purchase STLDI in the future will be impacted by these final rules. Data from the NAIC indicate that 235,775 individuals were covered by STLDI sold to individuals at the end of 2022.[304] As noted in section V.B.1 of this preamble, this figure does not capture the total number of individuals covered by STLDI throughout the year and does not include individuals covered by STLDI sold to or through associations, through which most policies appear to be sold.[305] As noted in section V.B.1 of this preamble, projections by CBO and JCT suggest that 1.5 million people could currently be enrolled in STLDI,[306] and CMS previously estimated that 1.9 million individuals would enroll in STLDI by 2023.[307] However, the CBO and JCT and CMS estimates were developed prior to the expansion of PTC subsidies provided through the ARP and the IRA, which likely supported increased enrollment in individual health insurance coverage purchased on an Exchange in lieu of STLDI and other forms of health insurance not subject to the Federal consumer protections and requirements for comprehensive coverage, if only temporarily.[308] [309] The number of enrollees in STLDI also might have been affected by changes in State law or regulation that have occurred since the 2018 final rules were issued. The Departments received a comment

sheets/extended-access-opportunity-enroll-more-affordable-coverage-through-healthcaregov.

[297] U.S. House of Representatives Committee on Energy and Commerce (2020). "Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans Is Putting Americans at Risk," available at: *https://democrats-energycommerce.house.gov/newsroom/press-releases/ec-investigation-finds-millions-of-americans-enrolled-in-junk-health.*

[298] Corlette, Sabrina, Kevin Lucia, Dania Palanker, and Olivia Hoppe (2019). "The Marketing of Short-Term Health Plans: An Assessment of Industry Practices and State Regulatory Responses," Urban Institute, available at: *https://www.urban.org/research/publication/marketing-short-term-health-plans-assessment-industry-practices-and-state-regulatory-responses.*

[299] *See Healthinsurance.org* (2023). "Duration and Renewals of 2023 Short-Term Medical Plans by State," available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf.*

[300] Palanker, Dania, Maanasa Kona, and Emily Curran (2019). "States Step Up to Protect Insurance Markets and Consumers from Short-Term Health Plans," Commonwealth Fund, available at: *https://www.commonwealthfund.org/publications/issue-briefs/2019/may/states-step-up-protect-markets-consumers-short-term-plans.*

[301] *See Healthinsurance.org* (2023). "Duration and Renewals of 2023 Short-Term Medical Plans by State," available at: *https://www.healthinsurance.org/wp-content/uploads/2023/09/state-by-state-short-term-health-insurance.pdf.*

[302] *See* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[303] *See* Hall, Mark and Michael McCue (2022). "Short-Term Health Insurance and the ACA Market," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2022/short-term-health-insurance-and-aca-market.*

[304] National Association of Insurance Commissioners (2023). "2022 Accident and Health Policy Experience Report," available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

[305] Pollitz, Karen, Michelle Long, Ashley Semanskee, and Rabah Kamal (2018). "Understanding Short-Term Limited Duration Health Insurance," KFF, available at: *https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/.*

[306] Congressional Budget Office (2020). "CBO's Estimates of Enrollment in Short-Term, Limited-Duration Insurance," available at: *https://www.cbo.gov/publication/56622.* CBO and JCT projected that enrollment in STLDI would reach 1.6 million by 2028. *See* Congressional Budget Office (2019). "How CBO and JCT Analyzed Coverage Effects of New Rules for Association Health Plans and Short-Term Plans," available at: *https://www.cbo.gov/publication/54915.*

[307] CMS Office of the Actuary (2018). "Estimated Financial Effects of the Short-Term, Limited-Duration Policy Proposed Rule," available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/STLD20180406.pdf.*

[308] *See, for example,* Ortaliza, Jared, Krutika Amin, and Cynthia Cox (2022). "As ACA Marketplace Enrollment Reaches Record High, Fewer Are Buying Individual Market Coverage Elsewhere," KFF, available at: *https://www.kff.org/policy-watch/as-aca-marketplace-enrollment-reaches-record-high-fewer-are-buying-individual-market-coverage-elsewhere/.*

[309] Based on data from the NAIC, the number of individuals covered by STLDI rose from around 173,000 in 2021 to 236,000 in 2022, reversing the downward trend from 2020 to 2021. *See* National Association of Insurance Commissioners (2023). "2022 Accident and Health Policy Experience Report," available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

that also noted that the NAIC figure was likely an underestimate given that not all issuers report complete data to the NAIC. Another commenter—a State department of insurance—provided information about the number of individuals who had enrolled in STLDI in their State as of mid-2023. The Departments acknowledge that the NAIC figure likely underestimates the number of enrollees in STLDI, yet commenters did not offer additional data or information on the total number of consumers enrolled in STLDI across the country, and the Departments are not aware of another available source for these data.

Additionally, individuals who are currently enrolled in fixed indemnity excepted benefits coverage or who may choose to purchase or consider purchasing such coverage in the future will be affected by these final rules. Although the Departments are unaware of a definitive source for the number of fixed indemnity policies sold nationwide, the NAIC reports the total number of "other non-comprehensive coverage" policies [310] sold in the individual market. These nearly 2.6 million policies or certificates, covering approximately 4 million individuals, include fixed indemnity products along with other insurance products, and provide a potential estimate of the number of potential fixed indemnity policies or certificates and number of covered lives in the individual market. The Departments sought comments on the number of consumers who would be affected by the fixed indemnity excepted benefits coverage provisions in the proposed rules. Some commenters referenced a survey of 39 issuers of fixed indemnity or specified disease products. The survey indicated that approximately 3.4 million individuals are currently covered by fixed indemnity products in the individual market and approximately 4.7 million individuals are currently covered by fixed indemnity products in the group market.[311] Several issuers that commented on the proposed rules also provided information on the number of consumers currently enrolled in their fixed indemnity or other supplemental insurance products, with one issuer indicating that 47,900 of its customers were enrolled in fixed indemnity insurance without being enrolled in comprehensive coverage. One association commenting on the rules estimated that the number of supplemental policies in force for school employees "is in the multi-millions."

Based on the NAIC and industry estimates, the number of individuals with individual market fixed indemnity excepted benefits coverage who could be affected by these final rules could be up to 4 million, and the number of individuals with group market fixed indemnity excepted benefits coverage who could be affected by these final rules could be up to 4.7 million. However, because it is not clear what percentages of the NAIC and industry estimates are specific to fixed indemnity excepted benefits coverage rather than fixed indemnity insurance in general, the number of individuals affected by the provisions for fixed indemnity excepted benefits coverage in these final rules is likely to be lower than these estimates.

These final rules may also indirectly impact consumers enrolled in comprehensive coverage because of the potential impact of increased enrollment in comprehensive coverage on individual and group market risk pools, premiums, plan offerings, or issuer participation. While the Departments are unable to estimate whether or how these final rules will impact plan offerings or issuer participation in the individual and group markets for comprehensive coverage, in sections V.B.2.c and V.B.2.e of this preamble, the Departments discuss the estimated effects of the provisions regarding STLDI included in these final rules on enrollment in and premiums for individual health insurance coverage purchased on an Exchange.

Issuers of STLDI and fixed indemnity excepted benefits coverage will be directly impacted by these final rules. The NAIC reported that there were at least 28 issuers of STLDI in the individual market across the U.S. in 2022 and at least 93 issuers of "other non-comprehensive coverage" (including fixed indemnity insurance) in the individual market across the U.S. in 2022.[312] Data regarding issuers of STLDI and "other medical (non-comprehensive)" coverage are only available for the individual market. The Departments anticipate that many of these issuers also offer coverage in the group market. The Departments sought comments on the number of entities that would be affected by the proposed rules, including the number of issuers and associations offering STLDI and fixed indemnity excepted benefits coverage, but did not receive any data from commenters on the number of issuers in the STLDI or fixed indemnity excepted benefits coverage market that would be affected. Based on the NAIC data, and assuming some overlap between issuers in the individual and group market, the Departments anticipate that at least 28 issuers of STLDI and at least 93 issuers of fixed indemnity excepted benefits coverage could be affected by the provisions being finalized in these final rules. However, the Departments note that this might overestimate the number of issuers of fixed indemnity excepted benefits coverage, given that the NAIC figure captures issuers of other forms of non-comprehensive medical coverage in addition to fixed indemnity insurance, and that even for those issuers of fixed indemnity insurance that are included in this figure, it is not clear what percentage of those issuers offer fixed indemnity excepted benefits coverage in particular.

Agents and brokers selling STLDI or fixed indemnity excepted benefits coverage will be impacted by these final rules. The Bureau of Labor Statistics estimates that there are 445,540 insurance agents nationwide, which includes agents and brokers that sell health insurance products in addition to other types of insurance (for example, life and property).[313] One professional association, which is estimated to represent one-third of active health insurance agents and brokers,[314] has approximately 100,000 members.[315] However, the Departments lack data

[310] *See* National Association of Insurance Commissioners (2023). "2022 Accident and Health Policy Experience Report," available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf* ("Other medical (non-comprehensive) coverage" includes "policies such as hospital only, hospital confinement, surgical, outpatient indemnity, intensive care, mental health/substance abuse, and organ and tissue transplant (including scheduled type policies), etc." It is further noted that "expense reimbursement and indemnity plans should be included" in this definition, but that "this category does not include TRICARE/CHAMPUS Supplement, Medicare Supplement, or FEHB Program coverage." Data from the NAIC regarding issuers of "other non-comprehensive coverage" are only available for the individual market.

[311] *See* AHIP–ACLI–BCBSA 2023 Survey: Fixed Indemnity and Specified Disease Plans, September 7, 2023, available at: *https://www.ahip.org/resources/ahip-acli-bcbsa-2023-survey.*

[312] National Association of Insurance Commissioners (2023). "2022 Accident and Health Policy Experience Report," available at: *https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf.*

[313] Bureau of Labor Statistics (2022). "National Occupational Employment and Wage Estimates," available at: *https://www.bls.gov/oes/current/oes413021.htm.*

[314] Karaca-Mandic, Pinar, Feldman, Roger, and Peter Graven (2016). "The Role of Agents and Brokers in the Market for Health Insurance," *Journal of Risk and Insurance*, available at: *https://onlinelibrary.wiley.com/doi/full/10.1111/jori.12139.*

[315] National Association of Benefits and Insurance Professionals (2023). "Who We Are," available at: *https://nabip.org/who-we-are.*

about the number of agents and brokers that currently enroll individuals in STLDI or fixed indemnity excepted benefits coverage and did not receive any additional data from commenters.

c. Benefits

Increase in consumer awareness. These final rules are expected to reduce the harm caused to consumers who are misled into enrolling in STLDI or fixed indemnity excepted benefits coverage as an alternative to or replacement for comprehensive coverage. The notice provisions being finalized in these final rules will improve consumer understanding of STLDI and fixed indemnity excepted benefits coverage in relation to comprehensive coverage. The Departments received some comments noting that STLDI policies are often marketed as a more affordable alternative to comprehensive coverage, and received many comments stating that STLDI policies exclude critically important health care services, as discussed in section III.A.1 of this preamble. Many commenters stated that the 2023 proposed rules would help consumers differentiate STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage when shopping for health insurance. Some commenters also stated that the notice provisions for STLDI and fixed indemnity excepted benefits coverage would help combat deceptive marketing practices and would improve consumer understanding of the different options available when shopping for insurance. One commenter stated that enrollees in STLDI policies are functionally uninsured due to the narrow benefits and design limitations that are often poorly understood by consumers. Although several commenters expressed concern about the improper marketing of fixed indemnity insurance, some commenters suggested that such improper marketing practices are limited to a few "bad actors" in the market. One commenter stated that concerns over widespread consumer confusion are unsupported, and that consumer confusion could be addressed by policy alternatives like increased enforcement of deceptive marketing laws or enhanced consumer awareness campaigns, rather than the provisions proposed in the 2023 proposed rules. The Departments agree that the notice provisions will help ensure individuals are made aware that STLDI and fixed indemnity excepted benefits policies are not comprehensive coverage. The Departments are of the view that the provisions finalized in these final rules will reduce the level of deceptive marketing of STLDI and fixed indemnity excepted benefits policies, reduce the harm from such deceptive marketing practices, and increase the overall awareness of coverage options that include the full range of Federal consumer protections. These provisions will also help consumers more easily distinguish between STLDI or fixed indemnity excepted benefits coverage and individual health insurance coverage, thereby mitigating the risk that they mistakenly enroll in STLDI or fixed indemnity excepted benefits coverage in lieu of comprehensive coverage. The Departments appreciate the suggestions related to increased enforcement of deceptive marketing laws, and enhanced consumer awareness campaigns, but are of the view that these actions alone would not sufficiently address consumer confusion related to the current structure of STLDI and fixed indemnity excepted benefit coverage.

Better health outcomes. Consumers who switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage are expected to have better access to health care, better consumer protections, and more robust benefits, and are therefore expected to experience better health outcomes. Several commenters stated that STLDI policies can limit access to health care and lead to negative health outcomes given the insufficient coverage of STLDI policies. Commenters stated that the inadequate coverage, particularly for individuals with chronic conditions, could lead to the use of high-cost services, such as emergency department visits or hospitalizations that could have been prevented if adequate care were accessible through their STLDI coverage. On the other hand, some commenters stated that enrollees in STLDI and fixed indemnity excepted benefits policies can benefit from receiving services provided by any provider and are not limited by provider networks established by issuers offering comprehensive coverage.[316] Some commenters suggested that the STLDI provisions could restrict patients' access to certain providers or reduce access to care in general. Other commenters suggested that the STLDI provisions could influence the composition of health care utilization and spending—because of the limited benefits or high cost-sharing requirements of most STLDI policies, enrollees in STLDI policies may underutilize preventive care and overutilize higher-cost care.

The Departments acknowledge that there may be individuals whose provider may not be in-network with an issuer offering comprehensive coverage, and that individuals may experience changes in access to certain providers if they switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage. However, given the limited benefits, limited consumer protections, and financial exposure associated with most STLDI and fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage), the Departments are of the view that individuals' overall financial risk would decrease and their overall access to health care would increase if they enrolled in comprehensive coverage. Furthermore, the Departments are of the view that overall health outcomes will improve for individuals who enroll in comprehensive coverage in lieu of STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage). For example, studies[317] that examined the potential impacts of State policies regulating STLDI found that individuals in States that prohibited or restricted the sale of STLDI policies had more favorable cancer diagnoses when compared to individuals in States that did not prohibit or restrict STLDI policies. In summary, if individuals enroll in comprehensive coverage instead of STLDI or fixed indemnity excepted benefits coverage, the Departments expect that they will have increased access to care, decreased exposure to major medical expenses, and improved health outcomes.

Potential increase in enrollment in comprehensive coverage. The Departments anticipate that these final rules will lead to an increase in enrollment in comprehensive coverage. The Departments expect that individuals will be less likely to wait until they have incurred major medical

[316] Issuers of STLDI and fixed indemnity excepted benefits coverage may also have provider networks, and one commenter (an issuer of STLDI) noted that their provider network has 1.5 million physicians and other health care professionals and approximately 7,000 hospitals and other facilities.

[317] *See* Barnes, Justin, Anne Kirchhoff, Robin Yabroff, and Fumiko Chino (2023). "State Policies Regulating Short-Term Limited Duration Insurance Plans and Cancer Stage at Diagnosis," *JNCI Cancer Spectrum*, Volume 7, Issue 5, available at: *https://doi.org/10.1093/jncics/pkad060*. *See also* Yang, Nuo Nova Nova, Jingxuan Zhao, Justin Michael Barnes, Anne C. Kirchhoff, Fumiko Chino, Robin Yabroff, and Xuesong Han (2023). "Association of Federal and State Policies Regulating Short-term Limited Duration Insurance (STLD) Plans and Later Cancer Stage at Diagnosis." *JCO Oncology Practice*, Volume 19, Issue 11, available at: *https://ascopubs.org/doi/abs/10.1200/OP.2023.19.11_suppl.197*.

expenses or developed a medical condition to look for opportunities to switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage. Increased enrollment in comprehensive coverage in lieu of enrollment in STLDI is also expected to reduce the number of coverage rescissions, claims denials, and coverage exclusions associated with STLDI. However, as noted earlier in this section V.B.b of this preamble, the expanded PTC subsidies provided through the ARP and the IRA have likely already resulted in increased enrollment in individual health insurance coverage purchased on an Exchange in lieu of STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage), so the immediate overall effects of these final rules on enrollment in, market stability of, and risk pools for comprehensive coverage are expected to be limited in 2024 and 2025.[318] The CMS Office of the Actuary (OACT) estimates that, relative to current law, the provisions regarding STLDI being finalized in these final rules will not affect enrollment in individual health insurance coverage purchased on an Exchange in 2024 and 2025, but will increase enrollment by approximately 60,000 people in 2026, 2027, and 2028.[319] Many commenters indicated that the STLDI provisions are likely to reduce premiums for individual health insurance coverage. Many commenters also pointed to the potential shift in enrollment from STLDI to individual health insurance coverage as having a potential impact on the risk pools for individual health insurance coverage.[320] The Departments agree with these comments and are of the view that the provisions for STLDI and fixed indemnity excepted benefits coverage being finalized in these final rules will lead to more stable markets and improved market risk pools for comprehensive coverage.

Reduction in financial risk for consumers. To the extent that these final rules lead to an increase in enrollment in individual health insurance coverage subject to the Federal consumer protections and requirements for comprehensive coverage in lieu of STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage), the Departments are of the view that these final rules will result in a reduction in out-of-pocket expenses, medical debt, and risk of medical bankruptcy for consumers switching to comprehensive coverage. These final rules could also lead to a reduction in potentially devastating surprise bills from out-of-network providers in emergency and certain other circumstances to the extent the rules lead to an increase in enrollment in individual health insurance coverage, which is subject to the surprise billing protections for consumers under the No Surprises Act. Many commenters agreed that the proposals being finalized in these final rules will support consumer protections. Many commenters also indicated that these final rules are critical to ensuring consumers' financial well-being and reducing their financial risk. Several commenters agreed that the proposed STLDI notice would ensure that consumers understand the type of coverage that they would be enrolling in and its limitations. Many commenters stated that STLDI policies expose enrollees to the risk of high out-of-pocket costs when an illness or injury occurs, and some commenters stated that this could lead to increased medical debt. One commenter indicated that families without comprehensive care are at risk of delaying care or going into debt. One commenter indicated that consumers may not realize how limited their STLDI coverage is until they are faced with high out-of-pocket costs for services commonly covered under comprehensive coverage. Commenters pointed to rehabilitation services, prescription drug costs, and cancer treatments as resulting in significantly higher out-of-pocket costs for consumers enrolled in STLDI when compared to comprehensive coverage. For example, the Departments reviewed a scenario study[321] that assessed the cost implications of a hypothetical consumer who enrolls in a typical STLDI policy and is later diagnosed with breast cancer. The study found that this hypothetical consumer would incur between $40,000 to $63,000 in out-of-pocket expenses, compared to less than $8,000 in a comprehensive coverage plan. While many commenters argued that fixed indemnity excepted benefits coverage reduces financial risk, other commenters argued that fixed indemnity excepted benefits coverage exposes individuals to financial risk when it is used as a substitute for comprehensive coverage. Lastly, some commenters specifically noted that the provisions regarding stacking of STLDI policies would benefit consumers by limiting circumvention of the provisions related to maximum duration, as discussed in section III.A.2 of this preamble. The Departments agree with these comments and are of the view that to the extent that consumers obtain comprehensive coverage in lieu of STLDI or fixed indemnity excepted benefits coverage, they are likely to experience lower out-of-pocket costs for their care. As noted in section V.B.2.a of this preamble, the Departments acknowledge that fixed indemnity excepted benefits coverage can reduce financial risk when used as a supplement to comprehensive coverage but remain concerned about the financial risk for individuals when it is used as a substitute for comprehensive coverage.

d. Costs

Increase in premiums. The Departments recognize that some

[318] *See, for example,* Ortaliza, Jared, Krutika Amin, and Cynthia Cox (2022). "As ACA Marketplace Enrollment Reaches Record High, Fewer Are Buying Individual Market Coverage Elsewhere," KFF, available at: *https://www.kff.org/policy-watch/as-aca-marketplace-enrollment-reaches-record-high-fewer-are-buying-individual-market-coverage-elsewhere/. See also* Ortaliza, Jared, Krutika Amin, and Cynthia Cox (2024). "Another Year of Record ACA Marketplace Signups, Driven in Part by Medicaid Unwinding and Enhanced Subsidies," KFF, available at: *https://www.kff.org/policy-watch/another-year-of-record-aca-marketplace-signups-driven-in-part-by-medicaid-unwinding-and-enhanced-subsidies/.*

[319] In developing these estimates, OACT assumed that STLDI would be significantly less expensive than individual health insurance coverage purchased on an Exchange (where available) and would be an attractive option for individuals and families with relatively low health care costs and little to no subsidies. Using their health reform model, OACT estimated that, under current law, about 60,000 people would move from individual health insurance coverage purchased on an Exchange to STLDI in 2026, when the additional PTC subsidies available through 2025 through the IRA expire. In addition, since those switching to STLDI are assumed to be healthier than average, the average premium for individual health insurance coverage purchased on an Exchange would increase by roughly 0.5 percent. Changing the maximum duration of an STLDI policy, certificate, or contract of insurance to no more than 4 months is expected to negate these effects.

[320] The Departments received an analysis from a commenter that estimated the potential impact of the STLDI provisions on enrollment and premiums in the individual market for comprehensive coverage. The analysis found that the STLDI provisions are likely to increase enrollment and lower premiums in the individual market for comprehensive coverage. The analysis utilized upper bound estimates of existing STLDI enrollment and analyzed varying scenarios of transition from STLDI coverage to individual health insurance coverage to estimate that such transitions could result in a 0.5 to 2 percent reduction in premiums. The commenter acknowledged that these impacts would vary by State given the different levels of STLDI regulations in States. Overall, the analysis notes that the net result is positive for consumers should there be a significant transition from STLDI coverage to individual health insurance coverage.

[321] American Cancer Society Cancer Action Network (2019). "Inadequate Coverage: An ACS CAN Examination of Short-Term Health Plans," available at: *https://www.fightcancer.org/sites/default/files/ACS%20CAN%20Short%20Term%20Paper%20FINAL.pdf.*

individuals with STLDI or fixed indemnity excepted benefits coverage who switch to individual health insurance coverage might incur higher premium costs depending on their choice of available Exchange and off-Exchange plans, their PTC eligibility (if applicable), and the amount of APTC they receive (if any).[322] Several commenters noted that the STLDI provisions could lead to higher premium costs for individuals if they switch to comprehensive coverage, and several commenters noted the low monthly premiums for STLDI relative to comprehensive coverage. One commenter acknowledged that STLDI has lower premiums because the Federal consumer protections and requirements for comprehensive coverage do not apply to this form of coverage. Some commenters stated that STLDI policies cover the select benefits certain consumers want. The Departments acknowledge that premiums for comprehensive coverage are generally higher than premiums for STLDI, but note that this is largely because comprehensive coverage offers more benefits with lower out-of-pocket costs. Further, as noted in section II.A of this preamble, comprehensive coverage for individuals has generally become more accessible and affordable in recent years, due in part to the expansion of PTC subsidies under the ARP and the IRA, and the provisions for STLDI finalized in these final rules are expected to put further downward pressure on gross premiums for individuals enrolled in individual health insurance coverage purchased on an Exchange. The Departments are of the view that any increase in costs is outweighed by the meaningful increase in benefits and consumer protections afforded to individuals enrolled in comprehensive coverage.

Loss of coverage. These final rules might also lead to an increase in the number of individuals without some form of health insurance coverage, if some individuals with STLDI purchased after the applicability date are no longer able to renew or extend their current policy, choose not to purchase a new policy from another issuer of STLDI, and can only obtain comprehensive coverage during an annual individual market open enrollment period, or choose not to purchase comprehensive coverage. Many commenters agreed with the Departments' analysis and noted that the provisions regarding STLDI coverage may reduce consumers' coverage options or lead to a loss of coverage or a coverage gap. Many commenters argued that restricting access to STLDI would not be appropriate for certain populations given their coverage needs (for seasonal employees working in another State, for example). These commenters noted that specific groups who benefit from STLDI policies are most likely to go without insurance as a result of the STLDI provisions, such as gig-economy workers, contract workers, college students, commercial truck drivers, and travel nurses. Some commenters suggested that the STLDI provisions could lead consumers to seek alternative forms of non-comprehensive coverage, including coverage offered in unregulated markets (for example, through health care sharing ministries). The Departments acknowledge that some individuals who purchase STLDI policies after the applicability date may lose coverage and must wait until the next annual individual market open enrollment period to purchase comprehensive coverage (for example, if an individual with STLDI purchased after the applicability date exhausts their renewal or extension options or is unable to enroll in STLDI offered by a different issuer outside of an open enrollment period) or may choose to become uninsured. Some individuals might also seek coverage in unregulated markets. Those individuals who become uninsured or obtain coverage in unregulated markets could face an increased risk of higher out-of-pocket expenses and medical debt, reduced access to health care, and potentially worse health outcomes. The Departments are of the view, however, that the overall risk that some individuals may become uninsured or lose coverage because of the above circumstances is outweighed by the fact that a substantial number of individuals will likely benefit as a result of the final rules' STLDI provisions. Overall, the Departments are of the view that STLDI serves better as a bridge between different sources of comprehensive coverage than as an alternative to comprehensive coverage.

Increase in health care spending. To the extent that these final rules lead to an increase in enrollment in comprehensive coverage, they might result in an increase in overall health care utilization and spending, given that comprehensive coverage tends to have higher loss ratios and actuarial values and generally offers lower cost-sharing requirements and more generous benefits.[323]

Impact on States. The Departments solicited comments on the magnitude of the costs that States might incur associated with enacting new legislation, implementing new laws, and updating existing regulations regarding STLDI and fixed indemnity excepted benefits coverage. However, the Departments received little information about the potential costs to States associated with the provisions being finalized in these final rules. One commenter generally stated that the STLDI provisions would cause economic harm to States, but the commenter did not quantify or otherwise specify the type or extent of the economic impact on States. While no State is required to enact new legislation or change its regulations under the provisions being finalized in these final rules, the Departments anticipate that some States could incur a one-time cost if they do enact new legislation or update their regulations.

Many commenters also stated that the 2023 proposed rules would generate costs for States associated with evaluating and approving redesigned products and policy forms. The Departments acknowledge that some State departments of insurance may incur costs to the extent they need to review amended marketing materials and plan documents filed by issuers.

Costs to agents and brokers. The Departments sought information on the number of agents and brokers who sell STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage, respectively, and how their compensation might be affected by the provisions proposed in

[322] This might occur if premiums for STLDI are lower than premiums for individual health insurance coverage. One study, for example, showed that by screening out individuals with pre-existing conditions and providing fewer comprehensive benefits, issuers may be able to offer STLDI at rates 54 percent below those for (unsubsidized) comprehensive coverage. *See* Levitt, Larry, Rachel Fehr, Gary Claxton, Cynthia Cox, and Karen Pollitz (2018). "Why do Short-Term Health Insurance Plans Have Lower Premiums than Plans that Comply with the ACA?" KFF, available at: *https://files.kff.org/attachment/Issue-Brief-Why-Do-Short-Term-Health-Insurance-Plans-Have-Lower-Premiums-Than-Plans-That-Comply-with-the-ACA.*

[323] As noted earlier in this RIA, many STLDI and fixed indemnity excepted benefits policies offer limited benefits coverage and have relatively low actuarial values. Many STLDI and fixed indemnity excepted benefit coverage issuers spend a relatively high percentage of premium dollars on administration and overhead *See* National Association of Insurance Commissioners (2022). "Accident and Health Policy Experience Report for 2021," available at: *https://naic.soutronglobal.net/portal/Public/en-US/Search/AdvancedSearch.* Regarding the differences in cost-sharing requirements and out-of-pocket expenses between STLDI and individual health insurance coverage, *see, for example,* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

the 2023 proposed rules. Many commenters anticipated that the financial impacts of the proposals on agents and brokers would be significant, particularly given the relatively low commission rates that agents and brokers receive from the sale of Exchange plans as compared to STLDI and fixed indemnity insurance. Another commenter stated that the Departments' analysis lacked sufficient data to account for the potential impacts on agents and brokers. However, commenters did not provide information on the number of agents and brokers that sell STLDI or fixed indemnity excepted benefits coverage or data that would assist in quantifying the impact of the provisions proposed in the 2023 proposed rules on agents and brokers. Nevertheless, the Departments acknowledge that the provisions being finalized in these final rules may affect agents and brokers if there is an impact on enrollment in STLDI or fixed indemnity excepted benefits products. There is the potential for agent and broker compensation associated with the sale of STLDI or fixed indemnity excepted benefits coverage to be negatively affected if there is a reduction in the sale of these types of coverage. There is also the potential for agent and broker compensation associated with the sale of individual health insurance coverage to be positively affected if there is an increase in sales of that coverage.

Costs to issuers. In the 2023 proposed rules, the Departments explained they expected that issuers would incur minimal costs associated with the notice provisions. The Departments also expected that since issuers change their policy documents routinely, the costs to issuers to make changes in response to these final rules would be part of issuers' usual business costs. However, many commenters stated that issuers would incur operational costs associated with the provisions for fixed indemnity excepted benefits coverage proposed in the 2023 proposed rules (to make necessary updates to systems and processes, and other administrative tasks, for example). Many commenters noted the costs to refile documents with State departments of insurance, obtain State approvals, and ensure compliance, and the costs associated with new policy issuance, marketing, enrollment, and administration. While one commenter provided an estimate of the overall costs of implementing all of the provisions for fixed indemnity excepted benefits coverage proposed in the 2023 proposed rules, no commenter provided estimates of the costs associated with the provisions for STLDI or estimates specific to the notice provisions for STLDI and fixed indemnity excepted benefits coverage proposed in the 2023 proposed rules.

The Departments acknowledge these comments and anticipate that issuers will incur one-time costs to modify their products and plan documents to comply with the provisions for STLDI and fixed indemnity excepted benefits coverage that are being finalized in these final rules, with issuers also incurring costs related to filing amended marketing materials and plan documents with State departments of insurance. These costs are expected to vary by issuer depending on the number of States in which they offer products, State law requirements for STLDI or fixed indemnity excepted benefits coverage, the number of products they offer, and the overall scale of their operations.[324] These costs will include the costs associated with the notice provisions. Using wage information from the Bureau of Labor Statistics to account for median labor costs (including a 100 percent increase for the cost of fringe benefits and other indirect costs),[325] the Departments estimate that, on average for each issuer, a business operations specialist will need 4 hours (at an hourly labor cost of $73.06), an administrative assistant will need 4 hours (at an hourly labor cost of $42.38), and a web developer will need 8 hours (at an hourly labor cost of $75.56) to revise or place the notice that must be displayed in their marketing, application, and enrollment materials (including on websites) and in the individual market also to place the notice in the policy, certificate, or contract of insurance, to come into compliance with these final rules. The average cost per issuer to comply with the notice provisions is estimated to be approximately $1,066.[326] As noted earlier in this RIA, the NAIC estimates that there are currently 28 issuers of STLDI in the individual market and 93 issuers of "other medical (non-comprehensive)" coverage in the individual market, which include fixed indemnity insurance. Therefore, using the NAIC estimates, the total one-time cost to issuers of STLDI and fixed indemnity coverage to comply with the notice provisions will be at least approximately $129,015.[327]

e. Transfers

Transfers associated with transitions to comprehensive coverage. Individuals currently enrolled in STLDI may be healthier—on average—than individuals enrolled in comprehensive coverage, because comprehensive coverage is subject to Federal consumer protections and requirements for comprehensive coverage that prohibit those plans from excluding individuals or charging higher premiums on the basis of health status, gender, and other factors, whereas STLDI policies do not have to comply with these requirements and are typically subject to medical underwriting. These final rules are expected to cause some individuals with relatively low health care costs to enroll in individual health insurance coverage in lieu of STLDI, which is expected to improve the risk pools for individual health insurance coverage and lead to lower overall average premiums for individual health insurance coverage.

CMS previously estimated that gross premiums for individual health insurance coverage purchased on an Exchange in 2022 would be 6 percent higher under the 2018 proposed rules than they would have been in the absence of those rules.[328] CBO and JCT previously estimated that the 2018 final rules for STLDI, in conjunction with changes made through the 2018 Department of Labor rule entitled "Definition of 'Employer' Under Section 3(5) of ERISA—Association Health Plans,"[329] would increase premiums in the individual and small group health insurance coverage markets by around 3 percent.[330] An analysis of individual health insurance coverage rate filing materials for 2020 also found that the few issuers that explicitly included a premium adjustment because of the 2018 final rules increased premiums by

[324] The Departments do not have enough data or information to quantify these costs.

[325] *See* Bureau of Labor Statistics (2022). "National Occupational Employment and Wage Estimates," available at: *https://www.bls.gov/oes/current/oes_nat.htm.*

[326] (4 business operation specialist hours * $73.06) + (4 administrative assistant hours * $42.38) + (8 web developer hours * $75.56) = $1,066.24.

[327] (28 STLDI issuers + 93 issuers of other medical (non-comprehensive) coverage) * [(4 business operation specialist hours * $73.06) + (4 administrative assistant hours * $42.38) + (8 web developer hours * $75.56)] = $129,015.04.

[328] CMS Office of the Actuary (2018). "Estimated Financial Effects of the Short-Term, Limited-Duration Policy Proposed Rule," available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/STLD20180406.pdf.*

[329] 83 FR 28912 (June 21, 2018). This rule was vacated by the District Court of D.C. in *State of New York, et al.* v. *United States Department of Labor, et al.*, 363 F.Supp.3d 109 (D.D.C. 2019).

[330] Congressional Budget Office (2019). "How CBO and JCT Analyzed Coverage Effects of New Rules for Association Health Plans and Short-Term Plans," available at: *https://www.cbo.gov/publication/54915.*

between 0.5 percent and 2 percent in 2020.[331] These analyses suggest that these final rules should have an effect in the opposite direction, reducing gross premiums for individual health insurance coverage. OACT estimates that the provisions regarding STLDI will not affect gross premiums for individuals with individual health insurance coverage purchased on an Exchange in 2024 and 2025, given the expanded PTC subsidies provided through the IRA, but will reduce gross premiums by approximately 0.5 percent in 2026, 2027, and 2028, after the expanded PTC subsidies have ended.[332]

Many commenters agreed with the Departments that enrollment in STLDI adversely affects the risk pools for individual health insurance coverage, leading to higher premiums for individual health insurance coverage. Specifically, one commenter stated that this adverse selection and its effects would particularly disadvantage individuals with preexisting conditions. Furthermore, one study suggests that the 2018 final rules had a negative effect on the risk pools for individual health insurance coverage.[333] As such, the Departments continue to be of the view that access to STLDI has negative effects on the risk pools for individual health insurance coverage.

Some commenters also noted that enrollment in STLDI in lieu of comprehensive coverage could lead to fewer issuers in the Exchanges or otherwise distort or destabilize the markets for comprehensive coverage, while one commenter stated that the impact of enrollment in STLDI on the markets for comprehensive coverage would be rather limited (as indicated by OACT's impact estimates). A few commenters suggested that the STLDI provisions could potentially harm the market for individual health insurance coverage due to a reduction in competition, for example, with one commenter suggesting that the 2018 final rules promoted issuer competition in the overall market.[334] The Departments disagree with these commenters and note that STLDI and individual health insurance coverage are two very different products that are generally subject to different laws and regulations, and issuers of individual health insurance coverage are unlikely to have changed their product offerings to compete with STLDI.

Some commenters stated that enrollment in fixed indemnity excepted benefits coverage can adversely affect the risk pools for comprehensive coverage. A few commenters stated that the impact of fixed indemnity excepted benefits coverage on the risk pools for individual health insurance coverage purchased on an Exchange is limited or nonexistent. While the Departments expect that the notice provisions being finalized in these final rules will encourage some individuals to enroll in comprehensive coverage instead of fixed indemnity excepted benefits coverage, the Departments do not expect such increased enrollment to have a significant impact on market risk pools and therefore expect a limited impact on premiums for comprehensive coverage, if any.

Transfers from the Federal Government to individuals. The provisions regarding STLDI are expected to reduce Federal PTC spending after the end of the expanded PTC subsidies provided through the IRA. Specifically, these provisions are expected to reduce gross premiums for individual health insurance coverage purchased on an Exchange and therefore lower per capita PTC spending. This effect is expected to be partly offset by an increase in the number of individuals enrolling in Exchange coverage that would be eligible to receive the PTC (by approximately 20,000 in 2026, 2027, and 2028). On net, OACT estimates that these provisions will have no impact on Federal spending on PTC in 2024 and 2025 given the expanded PTC subsidies provided through the IRA, but will reduce Federal spending on the PTC by approximately $120 million in 2026, 2027, and 2028.[335] This reduction in Federal spending on the PTC is viewed as a reduction in the amount of the transfer from the Federal Government to individuals.

Transfers among issuers, consumers, and providers. These final rules could lead to a transfer in the form of reduced out-of-pocket expenses from issuers to consumers who switch from STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) to comprehensive coverage, since more health care services would be covered under comprehensive coverage and the out-of-pocket expenses (such as cost-sharing requirements) for comprehensive coverage might be lower than out-of-pocket expenses for STLDI or fixed indemnity excepted benefits coverage.[336]

Some commenters suggested that the STLDI provisions could lead to an increase in uncompensated care provided by providers and facilities, to the extent they lead to an increase in the number of individuals without any form of health insurance coverage who are unable to pay providers and facilities on an out-of-pocket basis, which would be a transfer from providers and facilities to uninsured individuals. However, a few commenters suggested that the STLDI provisions could lead to a decrease in uncompensated care provided by providers and facilities, to the extent that individuals with STLDI enroll in comprehensive coverage (which would generally offer more benefits and lower cost-sharing requirements, and increased access to health care) in lieu of STLDI; this would be a transfer from issuers of comprehensive coverage to providers and facilities. One commenter also suggested that the fixed indemnity excepted benefits coverage proposals in the 2023 proposed rules could generate costs for providers regarding receipt of payments from patients, which would be a transfer from providers to these individuals. The Departments lack data that would allow for a quantification of

[331] Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[332] *See* section V.B.2.c of this preamble for a discussion of the enrollment effects that drive these premium changes.

[333] *See* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[334] The commenter cited a study that compared the trends in Exchange enrollment, premiums, and issuer participation in States that had additional restrictions on or prohibited STLDI and in States that fully permitted STLDI (in accordance with the 2018 final rules). The study concluded that States that fully permitted STLDI ". . . have lost fewer enrollees in the individual market, have had far more insurers offer coverage in the market, and have had larger premium reductions since the [2018 final rules] took effect," further noting that "the only States where individual market premiums have increased since 2018 are the five [S]tates that effectively prohibit short-term plans." *See* Blase, Brian (2021). "Individual Health Insurance Markets Improving in States that Fully Permit Short-Term Plans," Galen Institute, available at: *https://galen.org/assets/Individual-Health-Insurance-Markets-Improving-in-States-that-Fully-Permit-Short-Term-Plans.pdf.*

[335] In fiscal year terms, this would be a reduction in Federal spending of $90 million in 2026, $120 million in 2027, and $120 million in 2028.

[336] As noted in the Costs subsection of this RIA, regarding the differences in cost-sharing requirements and out-of-pocket expenses between STLDI and individual health insurance coverage, *see, for example,* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

these effects but acknowledge that there may be a potential increase in uncompensated care provided by providers and facilities given the previously-mentioned impact of these final rules on out-of-pocket expenditures discussed in section V.B.2.d of this preamble.

f. Uncertainty

As noted throughout this preamble, due to a lack of data and information, there are several areas of uncertainty regarding the potential impacts of these final rules. The Departments are unable to forecast how all of the provisions of these final rules will affect enrollment in STLDI and fixed indemnity excepted benefits coverage, as the Departments are uncertain how many individuals are currently enrolled in STLDI or fixed indemnity excepted benefits coverage, how many of those individuals will switch to comprehensive coverage, how many individuals will try to find another issuer of STLDI once their current policy ends, how many individuals will choose to remain enrolled in fixed indemnity excepted benefits coverage, or how many individuals will choose not to purchase any form of coverage.[337] As a result, there is also some uncertainty about the impacts on market risk pools, premiums, Federal expenditures on PTC, and on compensation for agents and brokers selling STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage. One commenter noted that the uncertainty in the estimates pertaining to the number of affected entities undermines the Departments' analysis of impacts.

The Departments sought comments on all of these areas of uncertainty regarding the impacts of the 2023 proposed rules and where possible incorporated data and information received during the comment period in estimating the impacts of these final rules. Despite the uncertainty discussed in this section and throughout this preamble, the Departments have enough data to be confident that the benefits of these final rules outweigh the costs, and that these final rules will help ensure that consumers can clearly distinguish STLDI and fixed indemnity excepted benefits from comprehensive coverage, protect market risk pools and stabilize premiums for comprehensive coverage, and promote access to affordable comprehensive coverage.

g. Health Equity Impact

The Departments stated in section II.B of the preamble to the 2023 proposed rules that due to the typical underwriting practices and plan eligibility requirements in the market for STLDI, individuals might face higher premiums or might not be able to purchase STLDI because of preexisting health conditions, gender, or other factors.[338] STLDI and fixed indemnity excepted benefits coverage policies typically do not cover certain essential health benefits including prescription drugs, mental health and substance use disorder services, or maternity services,[339] which could contribute to disparities in access to health care and health outcomes (regarding mental health, maternal health, or infant health, for instance).[340] Many commenters stated that issuers of STLDI policies are able to discriminate against individuals on the basis of health status or preexisting conditions, age, or gender.

Consumers with low health literacy, which disproportionately includes consumers with low incomes,[341] might also be misled into purchasing STLDI or fixed indemnity excepted benefits coverage under the mistaken impression that it would lower their out-of-pocket costs while providing comprehensive coverage with lower premiums. Consumers with low income or who are members of underserved racial and ethnic groups are more likely to be uninsured and face barriers in accessing care.[342] Individuals in these populations arguably face the greatest health and financial consequences if STLDI or fixed indemnity excepted benefits coverage (when used as a substitute for comprehensive coverage) proves inadequate. These individuals are also potentially most vulnerable to practices like post-claims underwriting and rescission that are common in the STLDI market, which could leave them without any coverage in a health crisis. Some commenters shared the Departments' concern over the disproportionate impact that non-comprehensive products may have on consumers with low incomes and consumers of underserved racial and ethnic groups. Some commenters indicated that individuals with low health literacy are disproportionately impacted by misleading and deceptive marketing practices, as discussed in section III.A of this preamble.

These final rules are expected to help address these health inequities by ensuring that consumers can more easily distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage and thereby encouraging enrollment in comprehensive coverage.

h. Regulatory Review Cost Estimation

If regulations impose administrative costs on entities (for example, the time needed to read and interpret rules), regulatory agencies should estimate the

[337] Previous studies have estimated the impact of the STLDI definition adopted in the 2018 final rules on enrollment in individual health insurance coverage, but in conjunction with the impact of elimination of the individual shared responsibility payment. *See* Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[338] *See, for example,* Barnes, Justin and Fumiko Chino (2022). "Short-term Health Insurance Plans Come Up Short for Patients with Cancer," *JAMA Oncology,* Volume 8, Issue 8, available at: *https://jamanetwork.com/journals/jamaoncology/article-abstract/2793127.*

[339] Dieguez, Gabriela and Dane Hansen (2020). "The Impact of Short-Term Limited-Duration Policy Expansion on Patients and the ACA Individual Market," Milliman, available at: *https://www.milliman.com/en/insight/the-impact-of-short-term-limited-duration-policy-expansion-on-patients-and-the-aca-individual-market.*

[340] *See, for example,* Hill, Latoya, Samantha Artiga, and Usha Ranji (2022). "Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them," KFF, available at: *https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/.*

[341] *See, for example,* Hill, Latoya, Samantha Artiga, and Usha Ranji (2022). "Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them," KFF, available at: *https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/.*

[341] *See, for example,* Rikard, RV, Maxine Thompson, Julie McKinney, and Alison Beauchamp (2016). "Examining Health Literacy Disparities in the United States: A Third Look at the National Assessment of Adult Literacy," *BMC Public Health,* Volume 16, Issue 1, available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5022195/. See also* Davis, Stacy, Jonathan Wischhusen, Steven Sutton, Shannon Christy, Emmanuel Chavarria, Megan Sutter, Siddhartha Roy, Cathy Meade, and Clement Gwede (2020). "Demographic and Psychosocial Factors Associated with Limited Health Literacy in a Community-based Sample of Older Black Americans," *Patient Education and Counseling,* Volume 103, Issue 2, available at: *https://doi.org/10.1016/j.pec.2019.08.026.*

[342] *See* Tolbert, Jennifer, Kendal Orgera, and Anthony Damico (2020). "Key Facts about the Uninsured Population," KFF, available at: *https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/. See also* Artiga, Samantha, Latoya Hill, Kendal Orgera, and Anthony Damico (2021). "Health Coverage by Race and Ethnicity, 2010–2019," KFF, available at: *https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/. See also* KFF (2021). "Adults Who Report Not Having a Personal Doctor/Health Care Provider by Race/Ethnicity," available at: *https://www.kff.org/other/state-indicator/percent-of-adults-reporting-not-having-a-personal-doctor-by-raceethnicity/. See also* KFF (2021). "Adults Who Report Not Seeing a Doctor in the Past 12 Months Because of Cost by Race/Ethnicity," available at: *https://www.kff.org/other/state-indicator/percent-of-adults-reporting-not-seeing-a-doctor-in-the-past-12-months-because-of-cost-by-raceethnicity/.*

total cost associated with regulatory review.[343] In the 2023 proposed rules, the Departments assumed that approximately 250 entities would review the 2023 proposed rules. The Departments acknowledged that the number of entities reviewing the 2023 proposed rules could be higher or lower than anticipated. The Departments ultimately received 571 unique comments on the 2023 proposed rules that pertained to the proposals for STLDI and fixed indemnity excepted benefits coverage, of which 247 commenters were identified as entities (for example, issuers, State insurance departments, industry associations, and advocacy organizations). Based on the comments received, the Departments now estimate that the 571 unique commenters that commented on the 2023 proposed rules, along with at least one additional individual from each of the 247 entities commenting on the 2023 proposed rules, will review these final rules. That is, the Departments estimate that at least 818 individuals will read and interpret these final rules.

Using wage information from the Bureau of Labor Statistics, for Business Operations Specialists (All Other), to account for median labor costs (including a 100 percent increase for the cost of fringe benefits and other indirect costs), the Departments estimate that the cost of reviewing these final rules will be $73.06 per hour.[344] The Departments estimate that it will take each reviewing individual approximately 6 hours on average to review these final rules, with an associated cost of $438.36 (6 hours × $73.06). Therefore, the Departments estimate that the (one-time) total cost of reviewing these final rules will be approximately $358,578 (818 × $438.36). The Departments sought comments on this approach to estimating the total burden and cost for interested parties to read and interpret the rules, and received one comment arguing that reading and understanding the rules would take far longer than the 4 hours estimated in the 2023 proposed rules. The Departments agree that it might take some reviewers longer than the previously estimated 4 hours, or the currently estimated 6 hours, to read and interpret the rules, but that an average estimate is reasonable.

[343] *See* Office of the Assistant Secretary for Planning and Evaluation (2017). "Guidelines for Regulatory Impact Analysis," available at: *https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.*

[344] *See* Bureau of Labor Statistics (2022). "National Occupational Employment and Wage Estimates," available at: *https://www.bls.gov/oes/current/oes_nat.htm.*

C. Regulatory Alternatives—Departments of Health and Human Services and Labor

In developing the proposed rules, the Departments considered various alternative approaches. The Departments considered leaving in place the duration standards for STLDI established in the 2018 final rules but concluded that the 2018 final rules' duration standards were too lengthy for the reasons described in section III.A.2 of this preamble. The Departments also considered proposing to limit the maximum duration of STLDI policies to a less-than-6-month period to minimize disruption for consumers in some (but not all) States that have implemented a less than-6-month period, to a less than-3-month period as implemented in the 2016 final rules, or otherwise shortening the maximum duration to a time period shorter than allowed under current regulations. However, as further discussed in in section III.A.2 of this preamble, the Departments ultimately decided to propose and finalize a maximum duration of no more than 4 months to align with the rules regarding the 90-day waiting period limitation and the 1-month reasonable and bona fide employment-based orientation period that is permitted under the ACA.

The Departments considered proposing to limit stacking of STLDI policies, whether sold by the same or different issuer. However, after considering the potential challenges issuers and State regulators would face in attempting to determine whether an individual had previously enrolled in an STLDI policy with a different issuer, the Departments decided to propose to limit stacking only where STLDI is sold to an individual by the same issuer and sought comments on whether to extend the limit on stacking to STLDI sold to an individual by issuers that are members of the same controlled group. Some commenters suggested limiting stacking of multiple or consecutive STLDI policies sold by issuers that are members of the same controlled group or sold to members of the same household. Other commenters supported the Departments preventing stacking of STLDI policies sold by unaffiliated issuers. The Departments decided that limiting the sale of STLDI policies offered by issuers that are members of the same controlled group would prevent issuers from using their corporate structure to circumvent the rules related to maximum duration, but it is not apparent to the Departments that limiting stacking across unaffiliated issuers or different members of the same household accomplishes any similar goal.

For new STLDI sold or issued on or after the effective date of the final rules, the Departments proposed an applicability date for the amendments to the Federal definition of STLDI that would apply for coverage periods beginning on or after the effective date of the final rules. Some commenters expressed concern that issuers of STLDI would need more time to complete a number of administrative tasks—such as evaluating plan designs, updating system processes, and re-filing policy forms with State regulators—and suggested the Departments finalize an applicability date between 90 days and 12 months after the effective date of the final rules. Other commenters were concerned about the potential for consumer confusion when STLDI is marketed and sold during the annual individual market open enrollment period. To provide more time for issuers to come into compliance with these final rules for new STLDI policies and ensure that STLDI with a longer maximum duration is not marketed during the next annual individual market open enrollment period, the Departments decided that for new STLDI sold or issued on or after September 1, 2024, the revised Federal definition of STLDI under these final rules will apply for coverage periods beginning on or after September 1, 2024. This will allow consumers who enroll in a new STLDI policy on or after September 1, 2024, to avoid a gap between the STLDI policy and when comprehensive coverage purchased during the next individual market open enrollment period will begin.

The Departments considered proposing a limit on the marketing or sale of STLDI during the annual individual market open enrollment period. The Departments are concerned that aggressive and deceptive marketing practices by some issuers have lured consumers, looking for comprehensive coverage, into enrolling in STLDI, exposing them to financial risk. The Departments appreciated the comments received regarding how the Departments can support State efforts to limit the marketing and/or sale of STLDI during the open enrollment period and will take these comments into consideration as the Departments consider potential actions they can take to address the marketing and sale of STLDI during the individual market open enrollment period.

With respect to the proposed amendments to the notices provided to consumers considering enrolling in or purchasing STLDI, the Departments

considered including a complete list of Federal protections that apply to consumers enrolled in comprehensive coverage versus STLDI. This approach would more fully distinguish STLDI from comprehensive coverage and highlight in greater detail the risks to consumers of enrolling in STLDI instead of comprehensive coverage. However, after a review of the comments, consulting with plain language experts and conducting consumer testing, the Departments are of the view that providing a complete comparison of protections that a consumer would forgo by enrolling in STLDI rather than comprehensive coverage would result in a lengthy, complex notice that could be difficult for the typical consumer to understand. Increasing the length and complexity of the notice would also increase burden for issuers to provide the notice on policy documents and marketing and application materials as required by these final rules. The Departments solicited comments on all aspects of the revised notice, including whether a different format or presentation would result in a more useful, consumer-friendly notice. For a more detailed discussion of the notices considered, please reference section III.A.4 of this preamble.

The Departments considered several options when finalizing the notice requirements for fixed indemnity excepted benefits coverage in the group market. HHS considered the same options when revising the content and standards for the consumer notice in the individual market. As discussed in section III.B.1 of this preamble, consideration was given to changes to the wording, appearance and timing related to the notice provisions. The Departments considered different applicability dates for these notices, including applying the notice to plan years (or in the individual market, coverage periods) (including renewals) beginning on or after the effective date of these final rules (as proposed), September 1, 2024 (which would align with the applicability date finalized in these rules for the STLDI notice provision), January 1, 2025, and later dates such as January 1, 2027. The Departments concluded that applying the notice to plan years (or in the individual market, coverage periods) (including renewals) beginning on or after January 1, 2025, strikes an appropriate balance between providing plans and issuers offering fixed indemnity excepted benefits coverage with additional time to add or update the notice and ensuring that the notices are present for new enrollments and renewals offered on a calendar year basis. The Departments are of view that a large proportion of group market fixed indemnity excepted benefits coverage, for which the notice will be new, are likely to be offered on a calendar year basis, as part of an employer's open enrollment period for their employees. In addition, one commenter suggested that the Departments should require an attestation from whomever sells fixed indemnity excepted benefits coverage, confirming that the risks and limitations were explained during the sale. The Departments are of the view that it would be more effective and efficient to provide all prospective enrollees with consistent messaging on all marketing, application, and enrollment materials (and, in the individual market, also on the first page of the policy, certificate, or contract of insurance). The Departments also declined to impose an attestation requirement based on the associated cost and administrative burden to plans, issuers, plan sponsors, agents, and brokers.

One commenter suggested that the Departments should explore additional consumer protection measures, such as requiring plans and issuers to provide prospective consumers with a complete and easily searchable schedule of benefits prior to purchase, as well as a longer free-look period in which an enrollee can cancel the plan for any reason at no cost. The Departments agree that these features would be beneficial and encourage plans and issuers to offer them to the extent feasible.

D. Paperwork Reduction Act

These final rules revise the Federal definition of STLDI to provide that a revised notice must be prominently displayed (in either paper or electronic form) in at least 14-point font on the first page of the policy, certificate, or contract of insurance and in any marketing, application, and enrollment materials, including for renewals or extensions (including on websites that advertise or enroll in STLDI). These notice provisions apply for both new and existing STLDI for coverage periods beginning on or after September 1, 2024.

These final rules also amend the regulations regarding fixed indemnity excepted benefits coverage in the individual market to provide that a revised notice must be prominently displayed (in either paper or electronic form) on the first page of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment (or reenrollment) materials. These final rules also amend the regulations regarding fixed indemnity excepted benefits coverage in the group market to provide that a notice must be prominently displayed (in either paper or electronic form) on the first page of any marketing, application, and enrollment (or reenrollment) materials. These notice provisions for group and individual market fixed indemnity excepted benefits coverage are applicable to both new and existing coverage with respect to plan years (in the individual market, coverage periods) beginning on or after January 1, 2025.

The Departments are providing the exact text for the STLDI and fixed indemnity excepted benefits coverage notices in these final rules, and the language will not need to be customized. The burden associated with these notices is therefore not subject to the Paperwork Reduction Act of 1995 in accordance with 5 CFR 1320.3(c)(2) because these notices do not contain a "collection of information" as defined in 44 U.S.C. 3502(3). Consequently, this document need not be reviewed by OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Departments solicited comments on the potential burden on issuers if the final rules were to include required notices with language that would need to be customized with State-specific information, as discussed in this preamble at section III.A.4 for STLDI and section III.B.1.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*) requires agencies to analyze options for regulatory relief of small entities and to prepare a regulatory flexibility analysis to describe the impact of a rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." The data and conclusions presented in this section amount to the Departments' final regulatory flexibility analysis under the RFA.

1. Need for Regulatory Action, Objectives, and Legal Basis

This rulemaking is authorized by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act, which authorize the Secretaries of the

Treasury, Labor, and HHS to issue such regulations as may be necessary or appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and title XXVII of the PHS Act.

These final rules address specific issues that are critical to ensuring that consumers can clearly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage and make better informed decisions about the coverage they chose to purchase. As discussed earlier in this RIA, STLDI and fixed indemnity insurance tend to offer limited benefits and have relatively low actuarial values when compared to comprehensive coverage. Because STLDI and fixed indemnity insurance are sold outside of the Exchanges and are generally not subject to the Federal consumer protections and requirements for comprehensive coverage, consumers may have limited information about the limitations, value, and quality of the coverage being sold, and it might be mistakenly viewed as a substitute for comprehensive coverage.

Generally, these final rules revise the Federal definition of STLDI for new policies, certificates, or contracts of insurance to limit their term to 3 months and maximum duration, within a 12-month period, to 4 months. Additionally, these final rules further revise the Federal definition of STLDI and amend the regulations regarding fixed indemnity excepted benefits coverage to provide that a notice for both new and existing STLDI and fixed indemnity excepted benefits coverage must be prominently displayed (in either paper or electronic form) on the first page of any marketing, application, and enrollment (or reenrollment) materials, as described in this preamble at sections III.A.5 and III.B.1.

These final rules will support the goals of the ACA by increasing access to affordable and comprehensive health coverage, strengthening health insurance markets, and promote better consumer understanding of coverage options.

2. Number of Affected Small Entities as Defined by the Regulatory Flexibility Act

The provisions in these final rules will affect issuers of STLDI, issuers of fixed indemnity excepted benefits coverage, and agents and brokers selling STLDI and fixed indemnity excepted benefits coverage. For purposes of analysis under the RFA, the Departments consider issuers of STLDI and issuers of fixed indemnity excepted benefits coverage that have average annual receipts of $47 million or less as small entities. Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[345] entities with average annual receipts of $47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from MLR annual report submissions for the 2021 MLR reporting year, approximately 87 out of 483 issuers of health insurance coverage nationwide had total premium revenue of $47 million or less.[346] However, it should be noted that over 77 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $47 million. The Departments expect this to be the case for issuers of STLDI and fixed indemnity excepted benefits coverage. As noted earlier in this RIA, the Departments are unable to precisely determine how many small issuers of STLDI and fixed indemnity excepted benefits coverage will be affected by these final rules. Nevertheless, the Departments note that the NAIC reported that there were at least 28 issuers of STLDI in the individual market across the U.S. in 2022 and at least 93 issuers of "other non-comprehensive coverage" (including fixed indemnity insurance) in the individual market across the U.S. in 2022.[347] Data regarding issuers of STLDI and "other medical (non-comprehensive)" coverage are only available for the individual market. The Departments have identified 2 issuers of STLDI and 3 issuers of fixed indemnity insurance that fall below the $47 million threshold and could potentially be impacted by these final rules.[348] These issuers will incur costs associated with the notice provisions and could also incur one-time costs to modify their products to comply with the provisions for STLDI and fixed indemnity excepted benefits coverage that are being finalized in these final rules and to file amended marketing materials and plan documents with State departments of insurance, as discussed further in section V.E.3 of this preamble. The Departments solicited comments on the number of small issuers of STLDI and the number of small issuers of fixed indemnity excepted benefits coverage but did not receive any additional information to inform the analysis.

For purposes of analysis under the RFA, the Departments consider agents and brokers that have average annual receipts of $15 million or less as small entities. Agents and brokers are classified under NAICS code 524210 (Insurance Agencies and Brokerages), with a size standard of $15 million or less. These rules may affect agents and brokers if there is an impact on enrollment in STLDI or fixed indemnity excepted benefits products. There is the potential for the agent and broker compensation [349] associated with the sale of STLDI and fixed indemnity excepted benefits coverage to be negatively affected if there is a reduction in sales of that coverage. There is also the potential for agent and broker compensation associated with the sale of individual health insurance coverage to be positively affected if there is an increase in sales of that coverage. However, due to a lack of data, the Departments were unable to precisely estimate how many agents and brokers might be affected by the 2023 proposed rules and the magnitudes of the potential changes in compensation.[350] The Departments solicited comments on the number of agents and brokers who sell STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage, respectively, and how their compensation might be affected by the 2023 proposed rules. Many commenters stated that the financial impacts of the proposed Federal definitions for STLDI and fixed indemnity excepted benefits coverage on agents and brokers would be significant, particularly given the relatively low commission rates that agents and brokers receive from the sale of Exchange plans as compared to STLDI and fixed indemnity insurance. Another commenter stated that the regulatory flexibility analysis lacked sufficient data to account for the

[345] Small Business Administration (2023). "Table of Size Standards (last updated March 2023)," available at: *https://www.sba.gov/document/support-table-size-standards.*

[346] Based on internal calculations. Source: CMS, Medical Loss Ratio Data and System Resources, available at: *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[347] *Id.*

[348] This was informed by a review of issuers' financial records ranging from 2018–2022.

[349] Compensation includes commissions, fees, or other incentives (for example, rewards or bonuses) as established in the relevant contract between an issuer and the agent or broker.

[350] Previously, in 86 FR 51730, 51756, the Departments noted that a total of 55,541 agents and brokers work with issuers. Many of these agents and brokers are likely to be employed by small entities.

potential impacts on agents and brokers. Commenters did not provide additional information on the number of agents and brokers that sell STLDI and fixed indemnity insurance or data that would assist in quantifying the impact of these final rules on agents and brokers. As noted throughout this preamble, and discussed in section V.B.2.f of this preamble, due to a lack of data and information, there are several areas of uncertainty regarding the potential market impacts of these final rules. As a result, there is also some uncertainty about the potential impact on the compensation of agents and brokers.

To summarize, there is some uncertainty about the impacts of these rules on the revenue of issuers of STLDI and fixed indemnity excepted benefits coverage and the compensation of agents and brokers selling STLDI and fixed indemnity insurance. Nevertheless, the Departments acknowledge that to comply with these final rules, issuers of STLDI fixed indemnity excepted benefits coverage will incur a cost and that agents and brokers may be impacted by these final rules due to the potential impacts on enrollment in STLDI or fixed indemnity excepted benefits products. A brief discussion of the regulatory alternatives is found in section V.E.4 of this preamble and a more detailed discussion of the regulatory alternatives considered is found in section V.C of this preamble.

3. Compliance Requirements and Costs

As discussed in section V.B.2.h of this preamble, the Departments estimate the one-time cost to review these final rules will be approximately $438 per entity (6 hours x $73.06). As noted in section V.B.2.d of this preamble, the Departments acknowledge that issuers will also incur one-time costs to modify their products to comply with the provisions for STLDI and fixed indemnity excepted benefits coverage that are being finalized in these rules and filing amended marketing materials and plan documents with State departments of insurance. These costs are expected to vary by issuer depending on the number of States in which they offer products, the number of products they offer, and the overall scale of their operations.[351] Issuers of STLDI and fixed indemnity excepted benefits coverage will incur costs associated with the notice provisions in these final rules, which the Departments estimate to be approximately $1,066 per issuer,[352] as described in section V.B.2.d of this preamble.

4. Duplication, Overlap, and Conflict With Other Rules and Regulations

The Departments do not anticipate any duplication, overlap, or conflict with other rules and regulations associated with these rules. These rules revise current regulations to ensure that consumers can clearly distinguish STLDI and fixed indemnity excepted benefits coverage from comprehensive coverage.

5. Significant Alternatives

The regulatory alternatives considered in developing these rules are discussed in section V.C of this preamble. The Departments are of the view that none of these alternatives would both achieve the policy objectives and goals of these final rules as previously stated and be less burdensome to small entities. The Departments did receive comments on alternative timelines for issuers to comply with the requirements (including small entities). The Departments decided to delay the applicability dates for certain provisions to provide more time for issuers (including small entities) to modify their products and implement the required changes while still achieving the objectives of these final rules. For a more detailed discussion of the regulatory alternatives considered, please refer to section V.C of this preamble.

6. Impact on Small Rural Hospitals

In addition, section 1102(b) of the Social Security Act requires agencies to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. The Departments welcomed comments on this and did not receive any comments specifically regarding the impact of the provisions proposed in the 2023 proposed rules on small rural hospitals. Many commenters did note that the provisions proposed in the 2023 proposed rules could increase the potential number of uninsured individuals and a few commenters indicated that hospitals may find themselves treating more uninsured patients that are unable to pay for the services rendered. While these final rules are not subject to section 1102 of the Social Security Act, the Departments are of the view that these final rules will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Special Analyses—Department of the Treasury

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a rule that includes any Federal mandate that may result in expenditures in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. That threshold is approximately $183 million in 2024. As detailed in section V.B.2.d of this preamble, the combined impact on State, local, or Tribal governments and the private sector is not expected to be above the $183 million threshold.

H. Federalism

Executive Order 13132 establishes certain requirements that Federal agencies must meet when they issue rules that impose substantial direct costs on State and local governments, preempt State law, or otherwise have federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy-making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC.

In the Departments' view, these final rules have Federalism implications because they may have direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among various levels of government. Health insurance issuers offering STLDI and plans and issuers

[351] The Departments do not have enough data or information to quantify these costs.

[352] (4 business operation specialist hours * $73.06) + (4 administrative assistant hours * $42.38) + (8 web developer hours * $75.96) = $1,066.24.

offering fixed indemnity excepted benefits coverage must meet the minimum Federal standards for such coverage not to be subject to the Federal consumer protections and requirements for comprehensive coverage. States with State requirements for STLDI or fixed indemnity excepted benefits coverage that do not follow the minimum Federal standards for such coverage, as amended by these final rules, may therefore choose to update their laws and regulations regarding STLDI or fixed indemnity excepted benefits coverage to align with the minimum Federal standards so that such coverage issued in the State is treated as exempt from the Federal consumer protections and requirements for comprehensive coverage.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating an employee benefit plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and sections 2724 and 2762 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a) and 148.210(b)) apply so that the Federal consumer protections and requirements for comprehensive coverage are not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a Federal requirement.[353] The conference report accompanying HIPAA, when this Federal preemption standard was first established for the requirements in title XXVII of the PHS Act, indicates that this is intended to be the "narrowest" preemption of State laws.[354]

These final rules define STLDI for purposes of the Code, ERISA, and the PHS Act. Insurance coverage that meets the definition of STLDI in these final rules will qualify for the exception to the Federal definition of individual health insurance coverage and be exempt from the Federal consumer protections and requirements applicable to comprehensive coverage. Nothing in these final rules prevents regulation of STLDI for purposes of State law. For example, States may determine whether to permit the sale of STLDI in their insurance markets. If a State law permits or requires an action that is inconsistent with the Federal definition of STLDI, any coverage offered pursuant to that State law that does not meet the standards set forth in these final rules would not qualify as STLDI under Federal law and would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage. For example, if a State were to prohibit policies issued in that State from including the Federal consumer notice, then coverage in that State that did not include the Federal consumer notice language would not qualify for the exclusion from the PHS Act definition of individual health insurance coverage and thus would be subject to the Federal consumer protections and requirements applicable to individual health insurance coverage.

Similarly, if a State law were to require the removal of language from the Federal consumer notice for fixed indemnity excepted benefits coverage finalized in these final rules, any policy issued in the State that did not include the Federal notice would not be considered fixed indemnity excepted benefits coverage for purposes of Federal law and thus would be subject to the Federal consumer protections and requirements applicable to comprehensive coverage.

Many commenters on the 2023 proposed rules discussed the federalism implications of the proposed provisions for STLDI and fixed indemnity excepted benefits coverage, as discussed in sections III.A.1 and III.B.1, respectively of this preamble.

The Departments continue to be of the view that there is a need for action regarding STLDI and fixed indemnity excepted benefits coverage at the Federal level given, among other factors, the need to promote consumer understanding of coverage options and ensure consumers do not mistakenly enroll in STLDI and fixed indemnity excepted benefits coverage as a substitute for comprehensive coverage, the prevalence of aggressive and deceptive sales and marketing practices, reports of increased enrollment in STLDI through out-of-State associations, and the potential inability of States to regulate and collect information about these associations.[355]

While developing these final rules, the Departments have attempted to balance States' interests in regulating health insurance issuers and their health insurance markets with Congress' intent to establish a general Federal framework for health insurance coverage, including the provision of certain key, uniform minimum protections to consumers enrolled in comprehensive coverage in every State. It is the Departments' view that by doing so they have complied with the requirements of Executive Order 13132.

I. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, this rule has been transmitted to the Congress and the Comptroller General for review.

Heather C. Maloy,

Acting Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Aviva Aron-Dine,

Acting Assistant Secretary (Tax Policy), Department of the Treasury.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Child support, Employee benefit plans, Health care, Health insurance, Infants and children, Maternal and child health, Penalties, Pensions, Privacy, Reporting and recordkeeping requirements.

[353] A similar preemption provision was established for the Exchange and other Federal health insurance requirements that are codified outside of title XXVII of the PHS Act. See sections 1311(k) and 1321(d) of the ACA.

[354] *See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018 and available at: *https://www.congress.gov/congressional-report/104th-congress/house-report/736/1.*

[355] Keith, Katie (2020). "New Congressional Investigation of Short-Term Plans," *Health Affairs*, available at: *https://www.healthaffairs.org/do/10.1377/forefront.20200626.227261/full/. See also* Curran, Emily, Dania Palanker, and Sabrina Corlette (2019). "Short-Term Health Plans Sold Through Out-of-State Associations Threaten Consumer Protections," Commonwealth Fund, available at: *https://www.commonwealthfund.org/blog/2019/short-term-health-plans-sold-through-out-state-associations-threaten-consumer-protections.*

45 CFR Parts 144 and 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Insurance companies, Penalties, Reporting and recordkeeping requirements.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

For the reasons stated in the preamble, the Department of the Treasury and the IRS amend 26 CFR part 54 as set forth below:

PART 54—PENSION AND EXCISE TAX

■ 1. The general authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ 2. Section 54.9801–2 is amended by revising the definition of "Short-term, limited-duration insurance" to read as follows:

§ 54.9801–2 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that meets the conditions of paragraph (1) of this definition.

(1) *Short-term, limited-duration insurance* means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that:

(i) Has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this paragraph (1)(i), a renewal or extension includes the term of a new short-term, limited-duration insurance policy, certificate, or contract of insurance issued by the same issuer, or if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance; and

(ii) Displays prominently on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

(2) For purposes of paragraph (1)(i) of this definition, the term "controlled group" means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code.

(3) If any provision of this definition is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such

holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of the definition and shall not affect the remainder thereof.

* * * * *

■ 3. Section 54.9831–1 is amended by adding paragraphs (c)(4)(ii)(D) and (c)(4)(iv) to read as follows:

§ 54.9831–1 Special rules relating to group health plans.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(D) For plan years beginning on or after January 1, 2025, with respect to hospital indemnity or other fixed indemnity insurance:

(*1*) The plan or issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

(*2*) If participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of the insurance, the notice described in paragraph (c)(4)(ii)(D)(*1*) of this section is prominently displayed in any marketing and reenrollment materials provided at or before the time participants are given the opportunity to reenroll in coverage.

(*3*) If a plan or issuer provides a notice satisfying the requirements in paragraphs (c)(4)(ii)(D)(*1*) and (*2*) of this section to a participant, the obligation to

provide the notice is considered to be satisfied for both the plan and issuer.

* * * * *

(iv) *Severability.* If any provision of this paragraph (c)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (c)(4) and shall not affect the remainder thereof.

* * * * *

■ 4. Section 54.9833–1 is revised to read as follows:

§ 54.9833–1 Applicability dates.

Sections 54.9801–1 through 54.9801–6, and 54.9831–1 and this section are applicable for plan years beginning on or after July 1, 2005. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 54.9801–2 applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 26 CFR 54.9801–2, revised as of April 1, 2023, continues to apply, except that paragraph (2) of the definition of *short-term, limited-duration insurance* in § 54.9801–2 applies for coverage periods beginning on or after September 1, 2024.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 5. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 6. Section 2590.701–2 is amended by revising the definition of "Short-term, limited-duration insurance" to read as follows:

§ 2590.701–2 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that meets the conditions of paragraph (1) of this definition.

(1) *Short-term, limited-duration insurance* means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that:

(i) Has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this paragraph (1)(i), a renewal or extension includes the term of a new short-term, limited-duration insurance policy, certificate, or contract of insurance issued by the same issuer, or if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance; and

(ii) Displays prominently on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

(2) For purposes of paragraph (1)(i) of this definition, the term "controlled group" means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended.

(3) If any provision of this definition is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to

entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of the definition and shall not affect the remainder thereof.

* * * * *

■ 7. Section 2590.732 is amended by adding paragraphs (c)(4)(ii)(D) and (c)(4)(iv) to read as follows:

§ 2590.732 Special rules relating to group health plans.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(D) For plan years beginning on or after January 1, 2025, with respect to hospital indemnity or other fixed indemnity insurance:

(*1*) The plan or issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

(*2*) If participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of the insurance, the notice described in paragraph (c)(4)(ii)(D)(*1*) of this section is prominently displayed in any marketing and reenrollment materials provided at or before the time participants are given the opportunity to reenroll in coverage.

(3) If a plan or issuer provides a notice satisfying the requirements in paragraphs (c)(4)(ii)(D)(1) and (2) of this section to a participant, the obligation to provide the notice is considered to be satisfied for both the plan and issuer.

* * * * *

(iv) *Severability.* If any provision of this paragraph (c)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (c)(4) and shall not affect the remainder thereof.

* * * * *

■ 8. Section 2590.736 is revised to read as follows:

§ 2590.736 Applicability dates.

Sections 2590.701–1 through 2590.701–8 and 2590.731 through 2590.736 are applicable for plan years beginning on or after July 1, 2005. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 2590.701–2 applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 29 CFR 2590.701–2, revised as of July 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in § 2590.701–2 applies for coverage periods beginning on or after September 1, 2024.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 146, and 148 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 9. The authority citation for part 144 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended.

■ 10. Section 144.103 is amended by revising the definition of "Short-term, limited-duration insurance" to read as follows:

§ 144.103 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that meets the conditions of paragraph (1) of this definition.

(1) *Short-term, limited-duration insurance* means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that:

(i) Has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this paragraph (1)(i), a renewal or extension includes the term of a new short-term, limited-duration insurance policy, certificate, or contract of insurance issued by the same issuer, or if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance; and

(ii) Displays prominently on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

BILLING CODE 4830–01–C

(2) For purposes of paragraph (1)(i) of this definition, the term "controlled group" means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended.

(3) If any provision of this definition is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to

entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of the definition and shall not affect the remainder thereof.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 11. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92.

■ 12. Section 146.125 is revised to read as follows:

§ 146.125 Applicability dates.

Section 144.103 of this subchapter and §§ 146.111 through 146.119, 146.143, and 146.145 are applicable for plan years beginning on or after July 1, 2005. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 144.103 of this subchapter applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 45 CFR 144.103, revised as of October 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in § 144.103 applies for coverage periods beginning on or after September 1, 2024.

■ 13. Section 146.145 is amended by adding paragraphs (b)(4)(ii)(D) and (b)(4)(iv) to read as follows:

§ 146.145 Special rules relating to group health plans.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(D) For plan years beginning on or after January 1, 2025, with respect to hospital indemnity or other fixed indemnity insurance:

(*1*) The plan or issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

BILLING CODE 4830–01–C

(*2*) If participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of the insurance, the notice described in paragraph (b)(4)(ii)(D)(*1*) of this section is prominently displayed in any marketing and reenrollment materials provided at or before the time participants are given the opportunity to reenroll in coverage.

(*3*) If a plan or issuer provides a notice satisfying the requirements in paragraphs (b)(4)(ii)(D)(*1*) and (*2*) of this section to a participant, the obligation to provide the notice is considered to be satisfied for both the plan and issuer.

* * * * *

(iv) *Severability.* If any provision of this paragraph (b)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (b)(4) and shall not affect the remainder thereof.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 14. The authority citation for part 148 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–11 300gg–91, and 300gg–92, as amended.

■ 15. Section 148.102 is amended by revising paragraph (b) to read as follows:

§ 148.102 Scope and applicability dates.

* * * * *

(b) *Applicability dates.* Except as provided in §§ 148.124, 148.170, and 148.180, the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 144.103 of this subchapter applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 45 CFR 144.103, revised as of October 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in § 144.103 applies for coverage periods beginning on or after September 1, 2024.

■ 16. Section 148.220 is amended by revising paragraph (b)(4) to read as follows:

§ 148.220 Excepted benefits.

* * * * *

(b) * * *

(4) Hospital indemnity or other fixed indemnity insurance only if—

(i) There is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage;

(ii) The benefits are paid in a fixed dollar amount per period of hospitalization or illness and/or per service (for example, $100/day or $50/visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage; and

(iii)(A) For coverage periods beginning on or after January 1, 2025, the issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment or reenrollment materials that are provided at or before the time an individual has the opportunity to apply, enroll or reenroll in coverage, and on the first page of the policy, certificate, or contract of insurance, in at least 14-point font, the language in the following notice:

BILLING CODE 4830–01–P

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

(B) For coverage periods beginning on or after January 1, 2015, and prior to January 1, 2025, the issuer continues to follow the notice provision in 45 CFR 148.220(b)(4)(iv), revised as of October 1, 2023.

(iv) If any provision of this paragraph (b)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (b)(4) and shall not affect the remainder thereof.

* * * * *

[FR Doc. 2024–06551 Filed 3–28–24; 8:45 am]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–C

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN ASSOCIATION OF ANCILLARY BENEFITS, A FLORIDA NOT-FOR-PROFIT CORPORATION, *Plaintiff,* v. XAVIER BECERRA, in his official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, JULIE A. SU, in her official capacity, as acting UNITED STATES SECRETARY OF LABOR, and JANET YELLEN, in her official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF THE TREASURY, *Defendants.*	§	Case No.

DECLARATION OF MICHELLE DELANY

Pursuant to 28 U.S.C. § 1746, I, Michelle Delany, under penalty of perjury declare as follows:

1. I am Michelle Delany. I am over the age of 18 and a U.S. citizen.
2. I make this Declaration supporting Plaintiff's Complaint at Law and for Injunctive Relief and Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction to stay the effective date and enforcement of the final rules of the United States Department of the Treasury, United States Department of Labor, and United States Department of Health and Human Services that set forth revisions to the definition of "short-term, limited-duration insurance" ("STLDI") for purposes of its exclusion from the definition of "individual health insurance coverage" in 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 144.
3. I am the Chief Financial Officer ("CFO") of the American Association of Ancillary Benefits ("AAAB"), where I have worked for over four years.
4. AAAB is a nonprofit trade association that serves the ancillary benefits industry on behalf of carriers, vendors, third-party insurance servicers and distributors, as well as to advocate for specialty carriers, prepaid legal services, and other niche products in the insurance business segment. AAAB members include industry leaders providing STLDI and fixed indemnity insurance ("FII") plans.
5. AAAB members are located throughout the country, including in the State of Texas. AAAB routinely conducts business in Texas, including hosting educational and regulatory seminars for its members.

6. In my role as CFO, I am familiar with the practice of AAAB members in the marketing and selling of STLDI plans to members of the public who seek alternative and/or supplemental coverage to satisfy their medical coverage needs in the future.

7. STLDI plans serve a key role in that they provide a vehicle/product for consumers to obtain health coverage for periods when they would otherwise have a gap in coverage, such as leaving one place of employment for another.

8. STLDI plans provide consumers with a less expensive option than Affordable Care Act (ACA) plans that may suit their personal and financial needs. STLDI Plans serve as a vital lifeline for individuals navigating transitions between ACA or employer sponsored plans, offering temporary healthcare coverage during periods of change. They provide crucial assistance for those encountering scenarios such as missing open enrollment periods or facing unexpected life events resulting in coverage gaps exceeding four months.

9. There are well over 200,000 STLDI plans written through AAAB's 15 association members. AAAB members work with and provide the STLDI plans and the platforms on which those products are sold to the consumer.

10. There are approximately 1,000 agents and brokers who market and sell STLDI plans for and through AAAB's membership.

11. I am aware of the Final Rule of the United States Department of the Treasury, United States Department of Labor, and United States Department of Health and Human Services that set forth revisions to the definition of "short-term, limited-duration insurance" (STLDI) for purposes of its exclusion from the definition of "individual health insurance coverage" in 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 144, and have reviewed it.

12. I am also aware of the Final Rule's redefinition that restricts STLDI plans to a strict three-month plan term with a one month renewal will have an immediate adverse effect on AAAB members and the public because it eliminates the necessary flexibility that comes with administering STLDI plans and is eliminating a product that competes with comprehensive ACA plans.

13. AAAB, its association members, the health insurance industry, and the public will suffer immediate and irreparable harm if the New Rule is allowed to become effective. It will massively and needlessly disrupt the business operations of AAAB, its members, and countless other employers. It will also affect members of the public by displacing coverage for hundreds of thousands of policyholders nationwide.

14. In accordance with 28 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

FURTHER AFFIANT SAYETH NAUGHT...

Executed on the 28 day of August, 2024

Michelle Delany

EXHIBIT 3

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9837]

RIN 1545–BO41

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB86

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, and 148

[CMS–9924–F]

RIN 0938–AT48

Short-Term, Limited-Duration Insurance

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule amends the definition of short-term, limited-duration insurance for purposes of its exclusion from the definition of individual health insurance coverage. This action is being taken to lengthen the maximum duration of short-term, limited-duration insurance, which will provide more affordable consumer choices for health coverage.

DATES:

Effective date: These final regulations are effective on October 2, 2018.

Applicability date: Insurance policies sold on or after October 2, 2018 must meet the definition of short-term, limited-duration insurance contained in this final rule in order to be considered such insurance.

FOR FURTHER INFORMATION CONTACT: Amber Rivers or Matthew Litton, Department of Labor, (202) 693–8335; Dara Alderman, Internal Revenue Service, Department of the Treasury, (202) 317–5500; David Mlawsky, Centers for Medicare & Medicaid Services, Department of Health and Human Services, (410) 786–1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline, at 1–866–444–EBSA (3272) or visit the Department of Labor's website (*http://www.dol.gov/ebsa*). In addition, information from the Department of Health and Human Services (HHS) on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*) and information on health reform can be found at *www.HealthCare.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

This rule finalizes amendments to the definition of "short-term, limited-duration insurance" for purposes of its exclusion from the definition of "individual health insurance coverage" in 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 144.

A. General Statutory Background and Enactment of PPACA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) [1] added title XXVII to the Public Health Service Act (PHS Act), part 7 to the Employee Retirement Income Security Act of 1974 (ERISA), and Chapter 100 to the Internal Revenue Code (the Code), providing portability and nondiscrimination rules with respect to health coverage. These provisions of the PHS Act, ERISA, and the Code were later augmented by other laws, including the Mental Health Parity Act of 1996,[2] the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008,[3] the Newborns' and Mothers' Health Protection Act,[4] the Women's Health and Cancer Rights Act,[5] the Genetic Information Nondiscrimination Act of 2008,[6] the Children's Health Insurance Program Reauthorization Act of 2009,[7] Michelle's Law,[8] and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA).[9]

PPACA reorganizes, amends, and adds to the provisions of Part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. PPACA added section 715 of ERISA and section 9815 of the Code to incorporate provisions of Part A of title XXVII of the PHS Act (generally, sections 2701 through 2728 of the PHS Act) into ERISA and the Code.

B. President's Executive Order

On October 12, 2017, President Trump issued Executive Order 13813 entitled "Promoting Healthcare Choice and Competition Across the United States." [10] This Executive Order states in relevant part: "Within 60 days of the date of this order, the Secretaries of the Treasury, Labor, and Health and Human Services shall consider proposing regulations or revising guidance, consistent with law, to expand the availability of [short-term, limited-duration insurance]. To the extent permitted by law and supported by sound policy, the Secretaries should consider allowing such insurance to cover longer periods and be renewed by the consumer."

C. 2017 Tax Legislation

Section 5000A of the Code, added by PPACA, provides that all non-exempt applicable individuals must maintain minimum essential coverage (MEC) or pay the individual shared responsibility payment.[11] On December 22, 2017, the President signed tax reform legislation into law.[12] This legislation includes a provision under which the individual shared responsibility payment under section 5000A of the Code is reduced to

[1] Public Law 104–191, 110 Stat. 1936 (August 21, 1996).

[2] Public Law 104–204, 110 Stat. 2944 (September 26, 1996).

[3] Public Law 110–343, 122 Stat. 3881 (October 3, 2008).

[4] Public Law 104–204, 110 Stat. 2935 (September 26, 1996).

[5] Public Law 105–277, 112 Stat. 2681–436 (October 21, 1998).

[6] Public Law 110–233, 122 Stat. 881 (May 21, 2008).

[7] Public Law 111–3, 123 Stat. 64 (February 4, 2009).

[8] Public Law 110–381, 122 Stat. 4081 (October 9, 2008).

[9] The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, was enacted on March 30, 2010. These statutes are collectively referred to as PPACA.

[10] 82 FR 48385.

[11] The eligibility standards for exemptions can be found at 45 CFR 155.605. Section 5000A of the Code and Treasury regulations at 26 CFR 1.5000A–3 provide exemptions from the requirement to maintain MEC for the following individuals: (1) Members of recognized religious sects; (2) members of health care sharing ministries; (3) exempt noncitizens; (4) incarcerated individuals; (5) individuals with no affordable coverage; (6) individuals with household income below the income tax filing threshold; (7) members of federally recognized Indian tribes; (8) individuals who qualify for a hardship exemption certification; and (9) individuals with a short coverage gap of a continuous period of less than 3 months in which the individual is not covered under MEC.

[12] Public Law 115–97, 131 Stat. 2054.

$0, effective for months beginning after December 31, 2018.

D. Short-Term, Limited-Duration Insurance

Short-term, limited-duration insurance is a type of health insurance coverage that was primarily designed to fill temporary gaps in coverage that may occur when an individual is transitioning from one plan or coverage to another plan or coverage. Section 2791(b)(5) of the PHS Act provides "[t]he term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance." [13] However, the PHS Act does not define short-term, limited-duration insurance. In 1997, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (together, the Departments), issued regulations implementing the portability and renewability requirements of HIPAA, which included definitions of individual health insurance coverage as well as short-term, limited-duration insurance.[14] Those regulations defined short-term, limited-duration insurance as "health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer's consent) that is less than 12 months after the original effective date of the contract." [15]

Short-term, limited-duration insurance is generally exempt from the Federal market requirements applicable to health insurance sold in the individual market because it is not considered individual health insurance coverage. For example, short-term, limited-duration insurance is not subject to the requirement to provide essential health benefits and it is not subject to the prohibitions on preexisting condition exclusions or lifetime and annual dollar limits. It is also not subject to requirements regarding guaranteed availability and guaranteed renewability.

To address the issue of short-term, limited-duration insurance being sold as a type of primary coverage, as well as concerns regarding possible adverse selection impacts on the risk pools for PPACA-compliant plans, the Departments published a proposed rule on June 10, 2016 in the **Federal Register** entitled "Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance." [16] The June 2016 proposed rule proposed changing the definition of short-term, limited-duration insurance that had been in place for nearly 20 years by revising the definition to specify that short-term, limited-duration insurance could not provide coverage for 3 months or longer taking into account any extensions that may be elected by the policyholder with or without the issuer's consent.[17]

The June 2016 proposed rule also proposed to require that the following notice be prominently displayed in the contract and in any application materials provided in connection with enrollment in short-term, limited-duration insurance, in at least 14 point type:

THIS IS NOT QUALIFYING HEALTH COVERAGE ("MINIMUM ESSENTIAL COVERAGE") THAT SATISFIES THE HEALTH COVERAGE REQUIREMENT OF THE AFFORDABLE CARE ACT. IF YOU DON'T HAVE MINIMUM ESSENTIAL COVERAGE, YOU MAY OWE AN ADDITIONAL PAYMENT WITH YOUR TAXES.[18]

After reviewing public comments and feedback received from stakeholders, on October 31, 2016, the Departments finalized the June 2016 proposed rule without change in a final rule published in the **Federal Register** entitled "Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance." [19]

On June 12, 2017, HHS published a request for information in the **Federal Register** entitled "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients," [20] which solicited public comments about potential changes to existing regulations and guidance that could promote consumer choice, enhance affordability of coverage for individual consumers, and affirm the traditional regulatory authority of the states in regulating the business of health insurance, among other goals. Several commenters stated that changes to the October 2016 final rule may provide an opportunity to achieve these goals. Consistent with many comments submitted on the June 2016 proposed rule, commenters stated that shortening the permitted length of short-term, limited-duration insurance policies had deprived individuals of affordable coverage options. One commenter explained that due to the increased costs of PPACA-compliant major medical coverage, many financially-stressed individuals may be faced with a choice between short-term, limited-duration insurance coverage and going without any coverage at all. One commenter highlighted the need for short-term, limited-duration insurance coverage among individuals who are between jobs. Another commenter explained that states have the primary responsibility to regulate short-term, limited-duration insurance and opined that the October 2016 final rule was overreaching on the part of the federal government.

In addition to considering these comments, the Departments also considered that, while individuals who qualify for premium tax credits (PTCs) under section 36B of the Code are largely insulated from premium increases for individual health insurance coverage (that is, the government, and thus federal taxpayers, largely bear the cost of the increases), individuals who are not eligible for PTCs are particularly harmed by increased premiums in the individual market due to a lack of other, more affordable alternative coverage options. Based on CMS data on Exchange-effectuated enrollment and payment,

[13] Sections 733(b)(4) of ERISA and 2791(b)(4) of the PHS Act provide that group health insurance coverage means "in connection with a group health plan, health insurance coverage offered in connection with such plan." Sections 733(a)(1) of ERISA and 2791(a)(1) of the PHS Act provide that a group health plan is generally any plan, fund, or program established or maintained by an employer (or employee organization or both) for the purpose of providing medical care to employees or their dependents (as defined under the terms of the plan) directly, or through insurance, reimbursement, or otherwise. There is no corresponding provision excluding short-term, limited-duration insurance from the definition of group health insurance coverage. Thus, any health insurance that is sold in the group market and purports to be short-term, limited-duration insurance must comply with applicable group health insurance requirements established under Part A of title XXVII of the PHS Act, part 7 of ERISA, and Chapter 100 of the Code.

[14] The definition of individual health insurance coverage (and its exclusion of short-term, limited-duration insurance) has some limited relevance with respect to certain provisions that apply to group health plans and group health insurance issuers over which the Departments of Labor and the Treasury have jurisdiction. For example, an individual who loses coverage due to moving out of an HMO service area in the individual market triggers a special enrollment right into a group health plan. *See* 26 CFR 54.9801–6(a)(3)(i)(B), 29 CFR 2590.701–6(a)(3)(i)(B), and 45 CFR 146.117(a)(3)(i)(B). Also, a group health plan that wraps around individual health insurance coverage is an excepted benefit if certain conditions are satisfied. *See* 26 CFR 54.9831–1(c)(3)(vii), 29 CFR 2590.732(c)(3)(vii), and 45 CFR 146.145(b)(3)(vii).

[15] 62 FR 16894 at 16928, 16942, 16958 (April 8, 1997); *see also* 69 FR 78720 (December 30, 2004).

[16] 81 FR 38019.

[17] 81 FR 38019, 38032.

[18] Id. at 38032.

[19] 81 FR 75316 (October 31, 2016).

[20] 82 FR 26885.

average monthly enrollment for individuals without PTCs declined by 1.3 million, or 20 percent, between 2016 and 2017.[21] Some of this decline is likely a response to increased premiums.[22] Further, in 2018, about 26 percent of enrollees (living in 52 percent of counties) have access to just one issuer in the Exchange.[23] Such monopoly markets, which are more predominant in rural counties, do not provide meaningful choice for consumers and cause premiums to be higher than they would be in a competitive market. Additionally, although the October 2016 final rule was intended to boost enrollment in individual health insurance coverage by reducing the maximum duration of coverage in short-term, limited-duration plans, it did not succeed in that regard. Rather, average monthly enrollment in individual market plans decreased by 10 percent between 2016 and 2017, while premiums increased by 21 percent.[24] Therefore, the Departments determined that the expansion of additional coverage options such as short-term, limited-duration insurance is necessary, as premiums have escalated and affordable choices in the individual market have dwindled.

Accordingly, in light of Executive Order 13813 directing the Departments to consider proposing regulations or revising guidance to expand the availability of short-term, limited-duration insurance, as well as in response to continued feedback from stakeholders expressing concerns about the October 2016 final rule, the Departments published a proposed rule on February 21, 2018 entitled "Short-Term, Limited-Duration Insurance" under which the Departments proposed to amend the definition of short-term, limited-duration insurance to provide (as did the regulations implementing HIPAA) that such insurance may have a maximum coverage period of less than 12 months after the original effective date of the contract, taking into account any extensions that may be elected by the policyholder without the issuer's consent.[25]

In addition, the Departments proposed to revise the content of the notice that must appear in the contract and any application materials provided in connection with enrollment in short-term, limited-duration insurance, to be prominently displayed (in at least 14 point type), and to read as follows:

THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN'T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH INSURANCE COVERAGE. ALSO, THIS COVERAGE IS NOT "MINIMUM ESSENTIAL COVERAGE". IF YOU DON'T HAVE MINIMUM ESSENTIAL COVERAGE FOR ANY MONTH IN 2018, YOU MAY HAVE TO MAKE A PAYMENT WHEN YOU FILE YOUR TAX RETURN UNLESS YOU QUALIFY FOR AN EXEMPTION FROM THE REQUIREMENT THAT YOU HAVE HEALTH COVERAGE FOR THAT MONTH.

Under the proposed rule, the final two sentences of the notice would only be required for policies sold on or after the applicability date of the final rule, if finalized, that have a coverage start date before January 1, 2019, because the individual shared responsibility payment is reduced to $0 for months beginning after December 2018.

The Departments proposed that the rule would be effective 60 days after publication of the final rule in the **Federal Register**, and with respect to the applicability date, the Departments proposed that policies sold on or after the 60th day following publication of the final rule would have to meet the definition of short-term, limited-duration insurance in the final rule in order to be considered short-term, limited-duration insurance. Further, the Departments proposed that group health plans and group health insurance issuers, to the extent they must distinguish between short-term, limited-duration insurance and individual health insurance coverage, must apply the definition of short-term, limited-duration insurance in the final rule as of the 60th day following publication of the final rule.

Request for Comments

The Departments requested comments on all aspects of the proposed rule, including whether the length of short-term, limited-duration insurance should be some other duration. Also, the Departments requested comments on any regulations or other guidance or policy that limits issuers' flexibility in designing short-term, limited-duration insurance or poses barriers to entry into the short-term, limited-duration insurance market. In addition, the Departments specifically sought comments on both the conditions under which issuers should be able to allow short-term, limited-duration insurance to continue for 12 months or longer with the issuer's consent and the revised notice.

The Departments requested comments on the economic impact analysis provided in the proposed rule, and welcomed other estimates of the increase in enrollment in short-term, limited-duration insurance under the proposal, and on the health status and age of individuals who would purchase these policies.

The comment period on the proposed rule ended on April 23, 2018. The Departments received approximately 12,000 comments. After careful consideration of these comments, the Departments are issuing these final rules.

II. Overview of the Final Regulations

After considering the public comments, the Departments are finalizing the proposed rule with some modifications. Under this final rule, short-term, limited-duration insurance means health coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account

[21] Centers for Medicare and Medicaid Services, "Trends in Subsidized and Unsubsidized Individual Health Insurance Market Enrollment", July 2, 2018. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-2.pdf.*

[22] Note, however, that the reduction in the number of unsubsidized enrollees is due to several different effects. As implied in the main text, some of the reduction is attributable to unsubsidized enrollees dropping coverage due to premium increases. Unsubsidized enrollees might also have left the Exchange because the labor market has improved, which might have resulted in increased availability of employer-sponsored coverage. In addition, because Exchange enrollees pay a fixed share of income for premiums with PTC covering the remainder, when premiums rise some unsubsidized enrollees become subsidized, even if enrollment does not change at all. Between February 2017 and February 2018, effectuated enrollment fell by about 209,000 among the unsubsidized but rose by 522,000 for the subsidized, suggesting some movement from unsubsidized to subsidized status without a change in enrollment. *See* "2017 Effectuated Enrollment Snapshot", June 12, 2017, available at *https://downloads.cms.gov/files/effectuated-enrollment-snapshot-report-06-12-17.pdf* and "Early 2018 Effectuated Enrollment Snapshot", June 2, 2018, available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-1.pdf.*

[23] Kaiser Family Foundation, "Insurer Participation on ACA Marketplaces, 2014–2018," November 10, 2017. Available at *http://www.kff.org/health-reform/issue-brief/insurer-participation-on-aca-marketplaces/.*

[24] Centers for Medicare and Medicaid Services, "Trends in Subsidized and Unsubsidized Individual Health Insurance Market Enrollment", July 2, 2018. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-2.pdf.*

[25] 83 FR 7437 (February 21, 2018).

renewals or extensions, has a duration of no longer than 36 months in total.

This final rule also retains the requirement that issuers of short-term, limited-duration insurance display one of two versions of a notice prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14-point type. However, the language of the notice in the final rule is revised to read as follows:

> This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

As under the proposed rule, the last two sentences of the notice are only required for policies sold on or after the applicability date of this final rule that have a coverage start date before January 1, 2019. As explained in more detail later in this preamble, in response to comments, the notice in the final rule contains additional specificity, including a list of health benefits that might not be covered. However, the Departments do not have evidence that short-term, limited-duration insurance policies have not historically or are unlikely to cover hospitalization and emergency services. Further, this final rule provides that the notice may contain any additional information as required by applicable state law and that the notice typeface should be in sentence case, rather than all capital letters.

Based on comments submitted, the Departments have also revised the estimates of the impact of short-term, limited-duration coverage on the individual health insurance market and the uninsured as explained further below. In addition, a severability clause has been added to this final rule. Finally, as was proposed in the proposed rule, this final rule is effective and applicable 60 days after publication in the **Federal Register**.

Comments on Authority

Several commenters questioned the Departments' legal authority with regard to various aspects of the proposed rule. One commenter stated that because the PHS Act exempts short-term, limited-duration insurance from the definition of "health insurance coverage," there is no delegation of Congressional authority giving HHS the power to define short-term, limited-duration insurance. Several commenters questioned whether the Departments have legal authority to define short-term, limited-duration insurance as having a maximum contract term of less than 12 months. One commenter stated that allowing such coverage to last nearly as long as individual health insurance coverage would be arbitrary, capricious, and not in accordance with law. Another commenter stated that the Departments failed to provide any reasonable justification for the change and expressed concern that short-term, limited-duration insurance will harm consumers and the individual market, will increase premiums for individual market plans, and will increase PTC expenditures. The commenter noted that despite acknowledging these potential outcomes of the proposed rule, the Departments stated that they are proposing this action to provide more affordable consumer choice for health coverage. The commenter stated that this does not suffice to explain the decision for a rule change that is inconsistent with the Departments' earlier position, cannot carry the force of law, and is not entitled to deference and therefore is arbitrary and capricious, and cannot stand. One commenter stated that none of the three preambles supporting the less-than-12-month duration (the 1997 rules, the 2004 rules and the proposed rule that this rule finalizes) provide a "reasoned explanation" for this choice as the maximum length of coverage. Another commenter stated that 3 months is a reasonable, ordinary-English meaning of the word "short," that the Departments' adoption of it in 2016 was well-reasoned, and that neither the facts nor the statute have changed, only a policy agenda inimical to PPACA is new.

Another commenter stated that the definition in the proposed rule is inconsistent with the statutory text of PHS Act section 2791(b)(5) because the proposed maximum duration for short-term, limited-duration insurance coverage is not sufficiently shorter than individual health insurance coverage to be consistent with any reasonable reading of the statutory phrase "short-term." This commenter also asserted that the proposed definition is inconsistent with PPACA, because an issuer meeting the proposed definition could avoid all PPACA insurance reforms, which would deprive consumers of PPACA's protections and damage individual market risk pools. Taking all this into consideration, the commenter asserted that the proposed definition is thus arbitrary and capricious.

The Departments disagree with these commenters that questioned our legal authority.

The Departments have clear statutory authority under the PHS Act to interpret undefined provisions of the PHS Act, ERISA, and the Code.[26] In order to determine the scope of individual health insurance coverage, which is essential to allow enforcement of the rules that apply to individual health insurance coverage, the Departments must give meaning to the term short-term, limited-duration insurance.[27] Relatedly, Congress provided the Secretaries of HHS, Labor and the Treasury with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the PHS Act.[28] Due to the absence of a statutory definition for the term short-term, limited-duration insurance, and the fact that the only reference to such coverage is as an exclusion from individual health insurance coverage, this includes the authority to issue regulations on short-term, limited-duration insurance to define it and set standards that distinguish it from individual health insurance coverage.

The Departments also disagree that the definition in the proposed rule and as revised in this final rule is inconsistent with PPACA. Both the proposed rule and the final rule establish federal standards for short-term, limited-duration insurance in a manner that clearly distinguishes such insurance from the individual health insurance coverage that is subject to PPACA's individual market requirements. Further, there are no explicit statutory standards governing

[26] *See* section 715 of ERISA and section 9815 of the Code, which incorporate provisions of Part A of title XXVII of the PHS Act (generally, sections 2701 through 2728 of the PHS Act) into ERISA and the Code. *See also*, section 104 of HIPAA. *See also*, sections 505 and 734 of ERISA, sections 2761 and 2792 of the PHS Act, section 1321(a)(1) and (c) of PPACA and section 7805 of the Code.

[27] As discussed in footnote 14, the definition of short-term, limited-duration insurance also has some relevance with respect to certain provisions that apply to group health plans and group health insurance issuers over which the Departments of Labor and the Treasury have jurisdiction.

[28] *See* section 2792 of the PHS Act.

the degree to which short-term, limited-duration insurance must vary from individual health insurance coverage, leaving it to the Departments to use their interpretive authority to distinguish between the two terms. Indeed, when the federal regulations for short-term, limited-duration insurance were first implemented in 1997, short-term, limited-duration insurance was considered to be health insurance coverage with a period of coverage that was less than 12 months, as under the proposed rule. That standard was in place for nearly two decades without objection. As demonstrated by the definition of short-term, limited-duration insurance in this final rule, short-term, limited-duration insurance and individual health insurance coverage are distinguished by the differences in their initial contract terms, the maximum duration of a policy itself, and the types of notice requirements applicable to each type of coverage. The two types of insurance are further distinguished with respect to whether the coverage is considered MEC. In the Departments' view, these differences are significant and sufficient to distinguish short-term, limited-duration insurance from individual health insurance coverage, and the definition of short-term, limited-duration insurance in this final rule is consistent with PPACA, is well reasoned, is clearly within the Departments' authority, and is therefore not arbitrary and capricious. Rather than deprive consumers of PPACA protections, this final rule expands access to additional, more affordable coverage options for individuals, including those who might otherwise be uninsured, as well as to those who do not qualify for PTCs or who otherwise find individual health insurance coverage unattractive. Consumers who want comprehensive, individual health insurance coverage as defined by PPACA will continue to be able to purchase such coverage on a guaranteed availability and guaranteed renewability basis in the individual market. As to the comment regarding whether the rule is justified, see the discussion in the Regulatory Impact Analysis in this final rule for updated estimates of the impact of enrollment in short-term, limited-duration insurance on consumers and the individual market.

As stated above, some commenters challenged the legal authority of the Departments to set a less-than-12 month maximum contract term, including extensions that may be elected by the policyholder without the issuer's consent. In this final rule, the Departments instead set a less-than-12-month maximum on the length of the initial contract term. The Departments would have had the authority to do the former (had we chosen to do so), and also have the authority to do the latter. As explained above, the Departments have authority to establish regulatory standards for short-term, limited-duration insurance, including setting a limit on the length of the initial contract term. The Departments have explained in the proposed rule and elsewhere in this final rule that this regulatory action is necessary and appropriate to remove federal barriers that inhibit consumer access to additional, more affordable coverage options and support state efforts to develop innovative solutions in response to market-specific needs.

This final rule recognizes the role that short-term, limited-duration insurance can fulfill, while at the same time distinguishing it from individual health insurance coverage by interpreting "short-term" to mean an initial contract term of less than 12 months and implementing the "limited-duration" requirement by precluding renewals or extensions that extend a policy beyond a total of 36 months. See below for a discussion of the rationale for the interpretation of the "limited-duration" requirement to mean no longer than 36 months. States remain free to adopt a definition with a shorter maximum initial contract term or shorter maximum duration (including renewals and extensions) for a policy to meet their specific market needs, including the adoption of strategies to mitigate adverse selection in the individual market.

One commenter stated that unlike health insurance products sold in the non-group market, short-term, limited-duration insurance is exempt from federal regulation and is subject only to state regulation and that the extent of CMS's statutory authority is to define what short-term, limited-duration insurance is. The commenter stated that the Departments have no legal authority to impose regulatory burdens or limitations on short-term, limited-duration insurance, such as the notice requirement.

The Departments agree with the commenter that short-term, limited-duration insurance is exempt from the PHS Act's individual market rules and is generally subject to state regulation. However, the Departments also have limited authority under the PHS Act to establish federal regulatory standards for short-term, limited-duration insurance, including standards related to the maximum length of the initial contract term, the maximum duration (including renewals and extensions) for a policy, and a consumer notice. This final rule establishes such federal standards for short-term, limited-duration insurance in a way that is necessary and appropriate to distinguish this coverage from individual health insurance coverage. As stated above, Congress provided the HHS, Labor, and Treasury Secretaries with explicit authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of the PHS Act.[29] The Departments believe that the federal regulatory definition of short-term, limited-duration insurance as set forth in this final rule, including the notice requirement, is necessary and appropriate to carry out the provisions of the PHS Act. As explained above, the Departments must give meaning to the undefined statutory term short-term, limited-duration insurance and the meaning must distinguish it from individual health insurance coverage. This is because the PHS Act imposes certain requirements on individual health insurance coverage, and does not impose those same requirements on short-term, limited-duration insurance. Further, the Departments believe it is necessary and appropriate for consumers considering the purchase of short-term, limited-duration insurance, and those actually purchasing such insurance, to be aware that such coverage is not subject to the federal individual market rules under the PHS Act. Therefore, one component of the federal standards for short-term, limited-duration insurance in this final rule is inclusion of the notice specified in this final rule, to inform applicants and enrollees that short-term, limited-duration insurance is not individual health insurance coverage and therefore is not required to meet the federal market requirements that apply to individual health insurance coverage. Defining short-term, limited-duration insurance in such a way that requires a short, standard description of how the coverage might vary from individual health insurance coverage allows for a clear determination by regulators that the policy is intended to be short-term, limited-duration insurance, facilitates compliance by issuers, and promotes ease of understanding by consumers. We further clarify that to the extent a health insurance policy sold to an individual in the non-group market includes the notice, and satisfies the other federal standards for short-term, limited-duration insurance in this final rule, it constitutes short-term, limited-duration insurance and is not subject to

[29] *See* section 2792 of the PHS Act.

the federal individual market rules under the PHS Act. As described elsewhere in this final rule, states can adopt a definition with a shorter maximum initial contract term and/or a shorter maximum duration of a policy, and can require issuers to provide additional information as part of the consumer notice.

The proposed rule did not address whether any aspect (or standard) in the definition of short-term, limited-duration insurance should be considered independent of other provisions, and thus severable, if such part of the definition were to be determined invalid. Although there were no comments that directly addressed severability, from the comments received on the proposed rule, the Departments recognize there is a possibility that some stakeholders may challenge the 36-month maximum duration standard in court. The Departments expect to prevail in any such challenge, as this final rule and each of the federal standards for short-term, limited-duration insurance finalized herein are legally sound. If a court should conclude that the 36-month maximum duration standard for short-term, limited-duration insurance in this final rule is invalid, the Departments wish to emphasize our intent that the remaining standards of the final rule will take effect and be given the maximum effect as permitted by law. Thus, we have added a severability clause as a new paragraph (4) to the final rule, which addresses two situations—one where the 36-month provision is invalidated "as applied," and the other where it is invalidated "facially." The severability provision reads as follows: "If a court holds the 36-month maximum duration provision set forth in paragraph (1) of this definition or its applicability to any person or circumstances invalid, the remaining provisions and their applicability to other people or circumstances shall continue in effect."

General Comments on the Proposed Rule

Many commenters generally agreed that short-term, limited-duration insurance plays an important role in providing temporary health coverage to individuals who would otherwise go uninsured. Most commenters also stated that such plans are not meant to take the place of comprehensive health insurance coverage, and allowing them to be marketed as a viable alternative to comprehensive coverage would subject uninformed consumers to potentially severe financial risks, and would siphon off healthier individuals from the market for individual health insurance coverage, thereby raising premiums for such coverage. Commenters who supported the proposed rule stated that it would allow purchasers of short-term, limited-duration insurance to obtain the coverage they want (excluding services they do not want) at a more affordable price for a longer period of time. These commenters explained that currently, enrollees have to reapply for short-term, limited-duration insurance every 3 months, have their deductibles reset every 3 months, and might lose coverage for conditions that develop during the initial 3 months. They also noted that many individuals may be unable to obtain more comprehensive coverage at the end of the 3-month coverage period because they may not qualify for a special enrollment period for individual health insurance coverage and might have a long time to wait for the next individual market open enrollment period.

The Departments agree that short-term, limited-duration insurance plays an important role in providing temporary valuable health coverage to individuals who would otherwise go uninsured. Short-term, limited-duration insurance can also provide a more affordable, and potentially desirable, coverage option for some consumers, such as those who cannot afford unsubsidized coverage in the individual market. This final rule balances the important role that short-term, limited-duration insurance plays in the market, while at the same distinguishing it from individual health insurance coverage and requiring issuers of short-term, limited-duration insurance to inform consumers of how coverage under the policy might differ from coverage under individual health insurance coverage. The rule does this by setting the maximum length of the initial contract term to less than 12 months, establishing the total maximum duration for a policy (including coverage during the initial contract term and renewals or extensions under the same insurance contract) of no longer than 36 months, and providing for a notice to inform consumers of how coverage under the policy might differ from coverage under individual health insurance coverage. Thus, under this final rule, issuers may offer coverage under a short-term, limited-duration insurance policy for up to a total of 36 months, without any medical underwriting or experience rating beyond that completed upon the initial sale of the policy (as long as the applicable notice is provided to consumers and the initial contract term is less than 12 months).

The Departments acknowledge that making short-term, limited-duration insurance more available, and for longer initial contract terms and periods of duration than is currently permitted, could have an impact on the risk pools for individual health insurance coverage, and could therefore raise premiums for individual health insurance coverage (see the discussion in the Regulatory Impact Analysis section). However, as discussed more fully below, we believe the critical need for coverage options that are more affordable than individual health insurance coverage, combined with the general need for more coverage options and choice, substantially outweigh the estimated impact on individual health insurance premiums.

Initial Contract Term for Short-Term, Limited-Duration Insurance

The proposed rule would have set a maximum length of short-term, limited-duration coverage, including any extensions that may be elected by the policyholder without the issuer's consent, of less than 12 months. Given that the proposed rule did not include a proposal to permit renewal periods in addition to or longer than the less-than-12-month period, we are addressing all comments related to the "less-than-12-month" aspect of the proposed rule as comments on the initial contract term. The Departments discuss and respond to comments related to renewals and extensions beyond the initial contract term, including comments on the permissible maximum duration for a policy (including renewals and extensions of the same insurance contract), later in this preamble. With respect to the maximum length of the initial contract term for short-term, limited-duration insurance, most comments suggested not extending the maximum duration beyond the current less-than-3-month maximum. Others suggested periods such as less than 6 or 8 months. Most commenters who supported extending the maximum initial contract term suggested it should be 364 days. A few commenters suggested more than 1 year. Other commenters stated that any short-term, limited-duration policy should end by December 31 of the calendar year in which the policy period commences, while others stated that the maximum duration should be 1 year or until December 31 of the calendar year in which the policy period commences, whichever occurs later. Other commenters stated that the maximum

length of the coverage should be left to the states.

As explained in the proposed rule, we proposed to return to the less-than-12-month standard in order to expand more affordable coverage options to consumers who desire and need them, to help individuals avoid paying for benefits provided in individual health insurance coverage that they believe are not worth the cost, to reduce the number of uninsured individuals, and to make available more coverage options with broader access to providers than certain individual health insurance coverage has. The Departments disagree with the commenters who supported a shorter maximum initial contract term. To the extent the initial contract term would be limited to a shorter duration, for example, 3 months, this would mean that every 3 months, absent renewability of the policy, an individual purchasing short-term, limited-duration insurance would be subject to re-underwriting if they did not have a renewal guarantee, and would possibly have his or her premium greatly increased as a result. The issuer could also decline to issue a new policy to the consumer based on preexisting medical conditions. Also, to the extent that the policy has a deductible, the individual would not get credit for money spent toward the deductible during the previous 3 months. In addition, to the extent that the policy excluded preexisting conditions for a specified period of time or imposed a waiting period on specific benefits, the individual might not get credit for the amount of the time he or she had the previous coverage, and thus the waiting period on preexisting conditions or on specific benefits would start over, leaving the consumer without coverage for the condition(s) or benefit(s) until the new waiting period expires. Although these circumstances would be somewhat mitigated if the maximum initial contract term was somewhat longer than less than 3 months, for example, less than 9 months, the Departments believe that mitigating these circumstances even further, by establishing a federal maximum initial contract term of less than 12 months, is preferable. The Departments find all of these to be compelling reasons in favor of permitting a maximum initial contract term of less than 12 months, rather than a shorter maximum initial contract term.

With respect to the comment that any short-term, limited-duration policy should end by December 31 of the calendar year in which the policy period commences, this could result in many such policies having an initial contract term of far less than 12 months, which for the reasons stated above, the Departments believe is not desirable. With respect to the comment that the maximum duration should be 1 year or until December 31 of the calendar year in which the policy period commences, the Departments do not believe that a policy with an initial contract term of 1 full year would satisfy the "short-term" component of short-term, limited-duration insurance, as it would have the same initial contract term as individual health insurance coverage.

The Departments agree that states remain free to adopt a definition with a shorter maximum initial contract term. The maximum initial contract term of less than 12 months established in this final rule provides a uniform federal standard for the initial contract term for short-term, limited-duration insurance. As explained in the proposed rule and elsewhere in this final rule, this standard was selected in order to promote access to health coverage choices in addition to individual health insurance coverage, which, as stated above, may or may not be the most appropriate or affordable policies for some individuals. Therefore, this rule sets a federal standard for the maximum initial contract term for short-term, limited-duration insurance. This federal standard defines the "short-term" component of short-term, limited-duration insurance as less than 12 months. The federal maximum duration for a policy (including renewals and extensions of the same insurance contract), discussed further below, implements the "limited-duration" component of short-term, limited-duration insurance.

Many commenters that opposed the extension of the maximum initial contract term for short-term, limited-duration insurance generally expressed concerns about the lack of protections for consumers who purchase short-term, limited-duration insurance. Some of these commenters stated that such insurance is not a viable option for people with serious or chronic medical conditions because of potential policy exclusions. Commenters also stated that short-term, limited-duration policies discriminate against those with serious illnesses and other preexisting conditions including mental health and substance abuse disorders, older consumers, women, transgender patients, persons with gender-identity-related health concerns, and victims of rape and domestic violence.

The commenters did not provide persuasive evidence for concluding that short-term, limited-duration policies discriminate against individuals. The Departments acknowledge that short-term, limited-duration insurance may not be suitable coverage for all individuals in all circumstances and that in some instances it may not provide coverage that is as comprehensive as individual health insurance coverage. However, short-term, limited-duration insurance can be a viable health insurance option for many people in many circumstances. Also, no individual is required to enroll in short-term, limited-duration insurance; rather, it is simply an additional, and likely more affordable, option that may be available to them. Individual health insurance coverage is unaffordable for many consumers, particularly those who do not qualify for PTCs. Of uninsured consumers visiting the *HealthCare.gov* website in the past year, 63 percent of those who did not purchase a plan cited high premiums as the primary reason not to purchase.[30] Furthermore, the availability of short-term, limited-duration insurance provides an additional choice for many consumers that exists side-by-side with individual market coverage, with the end result that individuals are provided with more choices and have the opportunity to purchase the type of coverage that is most desirable and suitable for the individual and/or her family. Additionally, many individuals who have health conditions for which they desire coverage that might be more comprehensive than what is available through short-term, limited-duration insurance, can access individual health insurance coverage on a guaranteed available and guaranteed renewable basis and, if enrollment is pursued through an Exchange and the individual is otherwise eligible, may qualify for the PTC to offset the cost of such coverage and, in some cases, cost-sharing reductions. PTCs and cost-sharing reductions generally are not available to purchasers of short-term, limited-duration insurance. However, states may be able to provide subsidies to purchasers of short-term, limited-duration insurance with funds provided under waivers authorized by section 1332 of PPACA[31] should they choose to do so and should the waiver satisfy all applicable requirements.

Also, states have flexibility to establish a different, shorter maximum initial contract term consistent with state law. In addition, these final rules require the prominent display of a notice in the contract and any application materials provided in connection with enrollment in short-term, limited-duration insurance to alert

[30] CMS Exchanges Trend Report, July 2, 2018.
[31] 42 U.S.C. 18052.

consumers about how coverage under the policy might vary from coverage under individual health insurance coverage. See the discussion below for an explanation of the changes the Departments are making to the required notice in this final rule in response to commenters' concerns about consumers' potential misunderstanding of some of those variations. These changes include a clarification that states have the flexibility to require additional consumer disclosures.

Many commenters who opposed the extension of the maximum initial contract term for short-term, limited-duration insurance expressed concern about what they viewed as a history of aggressive and deceptive marketing practices by individuals who market short-term, limited-duration insurance. One commenter stated that over the past 2 years, state regulators have seen an increase in complaints about such insurance, with consumers saying they were unaware their plan did not provide comprehensive coverage or that they could be refused a new policy at the end of the contract term. Many commenters provided examples of specific issues states were dealing with, such as issues with claims handling. In a 10-state survey conducted by the Commonwealth Fund [32] cited to by some commenters, state regulators noted an increase in complaints about brokers using deceptive practices to enroll people in short-term, limited-duration insurance over the phone. Some commenters also mentioned the low levels of health literacy, particularly among younger adults, and how this could exacerbate deceptive marketing practices by short-term, limited-duration insurance issuers and brokers. Several commenters stated that they did not want state laws prohibiting the sale of short-term, limited-duration insurance preempted.

This final rule establishes federal standards for short-term, limited-duration insurance only with respect to the maximum length of the initial contract term, the maximum duration of a policy (including renewals and extensions under the same insurance contract), and a consumer notice. States are free to regulate such coverage in every other respect. This contrasts with the federal regulation of individual health insurance coverage under the PHS Act, which touches many aspects of individual health insurance coverage, and therefore limits the degree to and areas in which states may regulate such coverage. This is yet another way in which the federal regulation of short-term, limited-duration insurance in this rule is different from individual health insurance coverage. In fact, several commenters (both in favor of, and opposed to, the proposed rule) said that states should retain the authority to regulate short-term, limited-duration insurance, and that such authority should not be preempted by the PHS Act. Several commenters requested the Departments to coordinate with the states on the regulation of short-term, limited-duration insurance. The Departments have considered those comments, and we acknowledge and respect states' authority to regulate the business of insurance. The Departments generally agree that states retain the authority to regulate short-term, limited-duration insurance and further note that this final rule does not change or otherwise modify the existing PHS Act preemption standard.[33] As such, states may shorten the length of the maximum initial contract term, the 36-month total maximum duration (including renewals or extensions) discussed further below, or both, although they may not lengthen them. Relatedly, as discussed later in this preamble, in this final rule, the Departments added language to the notice to alert consumers to how the coverage they are purchasing might vary from individual health insurance coverage and also added a clarification to the regulation text that states may also impose additional requirements with respect to the language in the consumer notice. States remain free to regulate short-term, limited-duration insurance. We also clarify that this final rule does not preempt any state laws prohibiting the sale of short-term, limited-duration insurance.

Renewability of Short-Term, Limited-Duration Insurance Coverage

The proposed rule provided that in determining whether an insurance contract had a duration of less than 12 months, extensions that may be elected by the policyholder without the issuer's consent were taken into account. The Departments solicited comments on the conditions under which issuers should be able to allow short-term, limited-duration insurance to continue 12 months or longer with the issuer's consent. The Departments also solicited comments on whether any processes for expedited or streamlined reapplication for short-term, limited-duration insurance that would simplify the reapplication process and minimize the burden on consumers may be appropriate; whether federal standards are appropriate for such processes; and whether any clarifications are needed regarding the application of the proposed definition of short-term, limited-duration insurance to such practices. For example, the proposed rule preamble noted that an expedited process could involve setting minimum federal standards for what must be considered as part of the streamlined reapplication process while allowing issuers to consider additional factors in accordance with contract terms. The Departments were also interested in information on any state approaches (including any approaches that states are considering adopting) to minimize the burden of the reapplication process for issuers and consumers.

Several commenters questioned the Departments' authority to permit the duration of short-term, limited-duration insurance to extend to 12 months or longer through renewal or extension of such policies. One commenter stated that "limited-duration" means these policies cannot be made guaranteed renewable. Several commenters stated that establishing a guaranteed renewability requirement for short-term, limited-duration insurance would be contrary to the plain language of the statute since short-term, limited-duration insurance is excluded from the statutory definition of individual health insurance coverage. One commenter stated that short-term, limited-duration insurance issuers should be permitted to sell a policy with a duration of less than 12 months, with a separate guaranteed renewability rider, allowing the customer to buy a new policy without underwriting. The commenter stated that the Departments have no statutory authority to prohibit or otherwise regulate such arrangements, and that the Departments have no authority to require guaranteed renewability, or prohibit it. One commenter suggested that issuers be allowed to sell multiple consecutive policies at the initial point of sale and be allowed to sell renewal options with and without preexisting conditions exclusions. One commenter stated that the term "short-term, limited-duration insurance" provides authority to define the length of time within which such insurance contracts must expire, but does not provide authority to limit how many contracts consumers enter into, or to regulate renewal guarantees. The commenter

[32] Dania Palanker, Kevin Lucia, Sabrina Corlette, Maanasa Kona, "Proposed Federal Changes to 'Short-Term Health Coverage Leave Regulation to States'", Commonwealth Fund, February 20, 2018. Available at *https://www.commonwealthfund.org/blog/2018/proposed-federal-changes-short-term-health-coverage-leave-regulation-state.*

[33] *See* section 2724 (formerly section 2723) of the PHS Act and 45 CFR 146.143 and 148.210. *See also* 62 FR 16894 at 16904 and 69 FR 78719 at 78739.

asserted that renewal guarantees are not "health insurance coverage," explaining that such guarantees protect against premiums increasing, but do not provide benefits consisting of items and services paid for as medical care and therefore, the Departments cannot regulate these contracts. Since renewal guarantees are not "health insurance coverage," the commenter asserted, it is reasonable to interpret the statute as not counting renewal guarantees against the time limit the Departments set for the contract for medical benefits. Another commenter stated that, should the final rule allow renewals, then changing the interpretation of this from the current rule, without support, would violate federal law.

Other commenters commented on the renewal of short-term, limited-duration insurance coverage from a policy perspective. Most such commenters who supported the proposed rule stated that short-term, limited-duration insurance should be permitted to be renewable, while those who opposed the proposed rule and some who agreed with lengthening the maximum period were opposed to permitting such policies to be renewable. One commenter stated that a federal mandate for automatic renewability would limit the rights of states and the ability of state regulators to determine the design, length, and sales practices of short-term, limited-duration insurance plans in a manner that best protects their consumers and markets. A few commenters addressed the extent to which, and the circumstances under which, individuals should be permitted to reapply for coverage under an expedited application process. Some of these commenters opposed such an expedited process, while others favored permitting it. One commenter suggested that short-term, limited-duration insurance issuers could design a less-than-12-month plan with an option to re-write at point of sale. This product would have a different set of underwriting questions at point of sale for the option. Upon expiration of the initial contract term, the issuer could elect to waive preexisting conditions and underwriting for the new less-than-12-month period. One commenter stated that federal standards should regulate short-term, limited-duration insurance policies, including standards for reapplication, while one commenter asserted that states should maintain authority to regulate the application and reapplication process. Another commenter that supported the proposed rule suggested further expanding the proposed federal standards to permit guaranteed renewals for short-term, limited-duration insurance.

Although some commenters questioned whether the Departments have authority to impose a guaranteed renewability requirement on short-term, limited-duration insurance, this final rule does not impose such a requirement. Rather, it permits, but does not require, issuers to renew or extend a short-term, limited-duration policy up to a maximum total duration of 36 months and still have such coverage considered short-term, limited-duration insurance. This rule does so by establishing a maximum duration of a short-term, limited-duration insurance policy (inclusive of the initial contract term and renewals or extensions under the same insurance contract) of no longer than 36 months.

Under this final rule, the total number of consecutive days of coverage under a single (that is, the same) insurance contract is the relevant metric to calculate the duration of the coverage to determine if it satisfies the 36-month maximum duration standard. In contrast, the total number of consecutive days of coverage under two or more (that is, separate) insurance contracts, even if one picks up where the last ended, is irrelevant to the 36-month maximum duration standard. The number of days of coverage in separate contracts is considered separately and the relevant question is whether each individual contract satisfies the 36-month maximum duration standard. Nothing in this final rule precludes the purchase of separate insurance contracts that run consecutively, so long as each individual contract is separate and can last no longer than 36 months.

With respect to the comment that, should the final rule allow renewals, then changing the interpretation of this from the current rule, without support, would violate federal law, the Departments note that the current rule (the October 2016 final rule) also allows renewals.[34] Accordingly, with regard to permitting renewals, there is no change of interpretation. The only difference between the two rules with respect to renewals is that the current rule allows renewals to the extent the total duration of coverage, including the initial contract term and any extensions or renewals, is less than 3 months, whereas this final rule allows renewals to the extent the maximum duration of a policy, including the initial contract term and renewals or extensions, is up to 36 months.

The Departments have determined that the 36-month limit on coverage, including the initial contract term, plus renewals or extensions (without limiting consecutive periods of *separate* coverage, as explained above) satisfies the "limited-duration" component of the statutory term "short-term, limited-duration insurance" (while the less-than-12-months limit on the initial contract term, discussed above, satisfies the "short-term" component of the term). The Departments note that Congress did not change the existing reference to short-term, limited-duration insurance as an exclusion from the PHS Act definition of "individual health insurance coverage" or otherwise address short-term, limited-duration insurance in PPACA, which indicates Congress was not concerned with short-term, limited-duration insurance existing side-by-side, at least under the standard in place prior to the October 2016 rule, with individual health insurance coverage. The Departments believe that a maximum duration of 36 months for short-term, limited-duration insurance is consistent with these two insurance markets existing side-by-side, while still giving meaning and effect to the "limited-duration" component of short-term, limited-duration insurance.

Likewise, the Departments' interpretation is consistent with the canon of statutory construction that disfavors rendering one or more statutory words or phrases redundant. Here, Congress used two terms: "short-term" and "limited-duration." The Departments have concluded that these two terms are best interpreted to refer to periods of time of differing length; if they both referred to a time period of the same length (for example, if the Departments interpreted both words to refer to a time period of less than twelve months), then one of the terms would be rendered redundant, or nearly so. The Departments likewise conclude that the term "limited-duration" refers to a longer time period than "short-term," because, while an insurance policy's duration is (absent cancellation) never shorter than its term, a policy's term can be shorter than its duration (if the policy is renewed or extended). Thus, the Departments conclude that the term "limited-duration" refers to a period of time that is longer than the time period contemplated by the term "short-term," and contemplates renewal of a short-term policy for a time period potentially

[34] The 1997 HIPAA rule similarly addressed extensions for short-term, limited-duration insurance (that is, short-term, limited-duration insurance was defined as health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions elected by the policyholder without the issuer's consent) that is less than 12 months after the original effective date of the contract). 62 FR 16894 (April 8, 1997).

longer than the maximum term length for which a short-term policy can be acquired (under this final rule, less than 12 months).

In determining the appropriate limits on the permissible range of renewals or extensions in giving meaning to the term "limited-duration," the Departments were informed by the stakeholder comments and other circumstances under which Congress authorized temporary limited coverage options. In particular, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) requires certain group health plans to extend group health coverage to certain individuals otherwise losing that coverage.[35] COBRA requires certain group health plan sponsors to provide a temporary continuation coverage option for a minimum of 18, 29, or 36 months, depending on the nature of the qualifying event that triggers the temporary coverage period. Under COBRA, the maximum period that COBRA coverage could extend is for a period of 36 months (where the qualifying event is employee enrollment in Medicare, divorce or legal separation, death of an employee, or loss of dependent child status (that is, "aging out" under the plan)). In certain circumstances, individuals experiencing a qualifying event such as job loss, which triggers an initial 18-month COBRA continuation coverage period, may experience a second qualifying event, making them eligible for a total maximum duration of 36 months of COBRA continuation coverage.

Similar to COBRA, short-term, limited-duration insurance also serves as temporary coverage for individuals transitioning between other types of coverage, and accordingly the Departments believe that it is reasonable to look to COBRA in giving meaning to "limited-duration," as both types of coverage serve an analogous purpose—that is, to provide temporary health coverage for individuals who are not currently eligible for or enrolled in comprehensive medical coverage, and are transitioning between types of coverage. Unlike COBRA, where Congress explicitly authorized a sliding scale of maximum duration periods, the Departments decline to adopt a sliding scale approach to the maximum duration period for short-term, limited-duration coverage. We adopt the approach outlined in this final rule for simplicity in the absence of explicit, staggered statutory maximums and because no party is required to renew or extend coverage for the maximum duration with respect to a short-term, limited-duration insurance policy; instead whether to provide coverage for the maximum period is left to the states and/or contracting parties. Accordingly, in establishing federal standards for short-term, limited-duration insurance, the Departments interpret the term "limited-duration" in a manner consistent with the temporary continuation coverage maximums available through COBRA and the somewhat similar statutory temporary continuation of coverage provisions under the Federal Employees Health Benefits Program,[36] which permit continuation of coverage for up to a maximum duration of 36 months.

Individuals may choose to purchase short-term, limited-duration insurance for a variety of different reasons, which may align with various COBRA qualifying events or not. Further, whereas COBRA describes the *minimum* period that certain group health plan sponsors *must* offer COBRA continuation coverage, these regulations describe the *maximum* coverage period during which insurers *may* renew a short-term, limited-duration insurance policy. However, the Departments conclude that the 36-month maximum coverage period is a reasonable and appropriate benchmark for interpreting the term "limited-duration." By allowing COBRA coverage to last up to 36 months in some circumstances, Congress recognized that 36 months qualifies as a temporary period of transition, during which coverage of limited duration may be useful. The Departments have strong policy considerations, as described elsewhere herein, for adopting an interpretation of the term "limited-duration" that provides a flexible period of insurance for individuals transitioning between other types of coverage, and COBRA's 36-month maximum provides precedent for a 36-month coverage period that is designed to be of limited duration. Therefore, in looking to COBRA as a guidepost for determining the maximum duration of short-term, limited-duration insurance (that is, the length of coverage under the initial contract term, plus renewals or extensions), the Departments believe the 36-month COBRA period, rather than the 18-month COBRA period, is more appropriate.

The Departments also believe permitting renewal or extension of a short-term, limited-duration insurance policy, but only to the extent the maximum duration of coverage under a policy is no longer than 36 months, serves to further distinguish such short-term, limited-duration insurance from individual health insurance coverage, which must be guaranteed renewable indefinitely, except under certain limited circumstances.[37] As noted earlier in this rule, states have flexibility to establish a different, shorter maximum duration for a short-term, limited-duration policy (including renewals or extensions) consistent with state law.

While the Departments did not specifically propose the 36-month maximum duration period for short-term, limited-duration insurance coverage in the proposed rule, comments were solicited on all aspects of the proposed rule, including whether the length of short-term, limited-duration insurance should be a different duration than less than 12 months, and the circumstances, if any, under which issuers should be allowed to continue (that is, renew) such coverage for 12 months or longer.[38] Comments were also solicited on a potential reapplication process for short-term, limited-duration insurance, including whether there should be federal standards for such a process. In response, the Departments received a wide range of comments indicating that short-term, limited-duration insurance coverage should be required to be guaranteed renewable, should be permitted to be renewed or extended for a designated period of time, and also that it should not be allowed to be renewed or extended beyond the initial contract term. We also received a number of suggestions regarding the adoption of federal standards governing any reapplication processes. After consideration of all the comments related to the issue of renewability or extensions, and for the reasons stated above, this final rule permits a short-term, limited-duration insurance policy to be renewed or extended so that the total duration of coverage under the policy may be up to 36 months.

Renewal guarantees generally permit a policyholder, when purchasing his or her initial insurance contract, to pay an additional amount, in exchange for a guarantee that the policyholder can elect to purchase, for periods of time following expiration of the initial contract, another policy or policies at some future date, at a specific premium that would not reflect any additional underwriting. In 2009, shortly before enactment of PPACA, one of the

[35] 26 U.S.C. 4980B(f), 29 U.S.C. 1161–1168, 42 U.S.C. 300bb–1—300bb–8.

[36] 5 U.S.C. 8905(a).

[37] Section 2703 of the PHS Act; *see also* 42 U.S.C. 300gg–42.

[38] *See*, for example, 83 FR 7440.

nation's largest health insurance issuers received regulatory approval from 25 states to offer renewal guarantees as a standalone product, for an annual premium equal to 20 percent of the cost of a guaranteed renewable health insurance policy.[39] With respect to the comments on renewal guarantees, to the extent a contract for health insurance coverage is extended or renewed, whether due to a renewal guarantee or otherwise, the period of health insurance coverage that is covered by the renewal or extension of the policy is counted toward the 36 month maximum duration, as to not do so would ignore the meaning of the statutory phrase "limited-duration." However, to the extent a contract does not provide health insurance coverage[40] and instead consists of a separate transaction or other instrument under which the individual can, in advance, lock in a premium rate in the future or the ability to purchase a new, separate short-term, limited-duration insurance policy at a specified premium rate at a future date without re-underwriting, such subsequent periods of coverage under the new, separate short-term, limited-duration insurance policies would not count toward the 36-month maximum. Through these mechanisms, it may be possible for a consumer to maintain coverage under short-term, limited-duration insurance policies for extended periods of time to protect themselves against financial vulnerabilities, such as developing a costly medical condition. The ability to purchase such instruments, which are essentially options to buy new policies in the future, is at present permitted under federal law, and this rule does nothing to forbid or permit such transactions. Furthermore, the Departments note that anyone, not just policyholders of short-term, limited-insurance, can purchase such instruments under current federal law (which this rule does not alter).

Similarly, the Departments also have not, and do not in this final rule, prohibit issuers from offering a new short-term, limited-duration insurance policy to consumers who have previously purchased this type of coverage, or otherwise prevent consumers from stringing together coverage under separate policies offered by the same or different issuers, for total coverage periods that would exceed 36 months.[41] The Departments are also significantly limited in their ability to take an enforcement action under the PHS Act market rules with respect to such transactions involving products or instruments that are not health insurance coverage.[42] As commenters mentioned, we also recognize that the mechanisms and means by which coverage may be extended or renewed may vary from state to state. Further, states can shorten the maximum duration for a short-term, limited-duration insurance policy, but cannot extend the maximum duration beyond the 36-month federal standard.

Therefore, as stated above, under this final rule, the total number of consecutive days of coverage under the *same* insurance contract is considered when calculating the duration of a policy for purposes of determining if the insurance satisfies the 36-month maximum duration federal standard. In contrast, the total number of consecutive days of coverage under *separate* insurance contracts is *not* considered when calculating the duration of coverage for such purpose. Rather, in such cases, the number of days of coverage under *each* contract of insurance is considered separately, to determine if the duration of the coverage under each contract satisfies the 36-month maximum duration standard, and coverage under each new contract commences a new period of coverage. The Departments generally defer to state law to determine the circumstances under which consecutive periods of coverage are under the same, or under separate, insurance contracts.

In addition to having authority to allow renewals or extensions for a maximum duration of up to 36 months, the Departments also determined there are sound policy reasons to provide the ability for renewals and extensions as set forth in the final rule. Many of these reasons are discussed above with respect to the less-than-12-month initial contract term maximum finalized in this rule. As many commenters pointed out, to the extent that the maximum duration of short-term, limited-duration insurance is limited to a relatively short period of time, for example, less than 3 months, or even less than 12 months, without permitting renewals or extensions, this would mean that every 3 months or every 12 months, an individual purchasing short-term, limited-duration insurance would be subject to re-underwriting, and would possibly have his or her premium greatly increased as a result. Also, to the extent the policy excluded preexisting conditions for a specified period of time or imposed a waiting period on specific benefits, the individual might not get credit for the amount of time he or she had the previous coverage. The issuer could also decline to issue a new policy to the consumer based on preexisting medical conditions. The Departments find all of these to be compelling reasons in favor of permitting renewals and extensions as set forth in the final rule, such that the maximum duration of coverage under a single short-term, limited-duration insurance policy may be 36 months (including renewal or other extension periods), as opposed to less than 12 months. While the Departments anticipate that some issuers will choose to provide renewals without the restrictions described above (such as providing renewals without premium increases and without re-setting preexisting condition exclusion waiting periods), we note that short-term, limited-duration insurance issuers are not required to do so under this final rule and may determine the terms of the renewal in the short-term, limited-duration insurance contract, subject to the definition of short-term, limited-duration insurance in this final regulation and any permissible state law variations. Further, in consideration of Congress' intent to exempt from the definition of individual health insurance coverage (and therefore, to exempt from the HIPAA and PPACA individual market requirements) short-term, limited-duration insurance, the Departments are not imposing a guaranteed renewability requirement on short-term, limited-duration insurance.

The Departments appreciate the comments and suggestions regarding simplified or expedited application and reapplication processes. The Departments decline to adopt or otherwise establish federal standards regarding such procedures at this time. Rather, the Departments defer to the states to define and regulate such practices.

Notice

In the proposed rule, the Departments proposed to revise the notice that must appear in the contract and any application materials provided in connection with enrollment in short-term, limited-duration insurance. The Departments noted concerns that short-term, limited-duration insurance policies that provide coverage lasting almost 12 months may be more difficult for some individuals to distinguish from coverage available in the individual

[39] Reed Abelson, "United Health to Insure the Right to Insurance," *New York Times*, December 2, 2008, *https://www.nytimes.com/2008/12/03/business/03insure.html*.

[40] *See* section 2792(b)(1) of the PHS Act.

[41] 81 FR 75318.

[42] However, the Departments may have the authority to regulate health insurance coverage issued pursuant to such an instrument.

market, which is typically offered on a 12-month basis. Accordingly, under the proposed rule, one of two versions of the following notice was proposed to be required to be prominently displayed (in at least 14 point type) in the contract and in any application materials provided in connection with enrollment:

THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN'T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH INSURANCE COVERAGE. ALSO, THIS COVERAGE IS NOT "MINIMUM ESSENTIAL COVERAGE". IF YOU DON'T HAVE MINIMUM ESSENTIAL COVERAGE FOR ANY MONTH IN 2018, YOU MAY HAVE TO MAKE A PAYMENT WHEN YOU FILE YOUR TAX RETURN UNLESS YOU QUALIFY FOR AN EXEMPTION FROM THE REQUIREMENT THAT YOU HAVE HEALTH COVERAGE FOR THAT MONTH.

Given that the individual shared responsibility payment is reduced to $0 for months beginning after December 2018, the Departments proposed that the final two sentences of the notice must appear only with respect to policies sold on or after the proposed applicability date of the rule, if finalized, that have a coverage start date before January 1, 2019.

The Departments solicited comments on this revised notice, and whether its language or some other language would best ensure that it is understandable and sufficiently apprises individuals of the nature of the coverage.

Many commenters generally supported the approach in the proposed rule that a short-term, limited-duration insurance policy must include such a notice. One commenter stated that the notice should not be part of the definition of short-term, limited-duration insurance, but should be a separate requirement that applies once a policy satisfies the short-term, limited-duration insurance definition. One commenter stated that requiring short-term, limited-duration insurance issuers to use one of two different notices (depending on the year) is burdensome to issuers and state regulators with respect to filing policies, and suggested developing one notice that could be used for all years. A few other commenters also more generally supported the use of just one type of notice. One commenter stated that issuers should be permitted to modify the notice to provide additional disclosures about their short-term, limited-duration insurance product, subject to state approval, while another commenter said that states should be permitted to prescribe their own notice language, with the federal language as a default for those states that fail to do so.

The Departments believe it is important and appropriate for issuers of short-term, limited-duration insurance to disclose the key potential characteristics of such insurance to applicants and policyholders. Consumers need as complete and accurate information as possible in order to make informed coverage purchasing decisions—whether it be for comprehensive, major medical coverage in the individual market or for short-term, limited-duration insurance, which can consist of a wide variety of coverage options. Therefore, the final rule retains the notice requirement, with some changes to content and style, as discussed below.

The Departments decline to adopt the suggestion that the notice should not be part of the definition of short-term, limited-duration insurance, but instead should be a separate requirement, once a policy satisfies the definition of short-term, limited-duration insurance. The Departments do not believe there is a compelling reason to so change the regulatory structure. The Departments also decline to adopt the suggestion that one disclosure notice be used, regardless of the year in which the policy is issued. As previously stated, the amount of the individual shared responsibility payment will be $0 for months beginning January 2019. For short-term, limited-duration policies covering any months before January 2019, the Departments believe it is critical that the disclosure notice inform applicants and policyholders that they could be liable for the individual shared responsibility payment, given the potential financial consequences for not maintaining MEC during that time. However, for policies not covering any such month, not only would such language be irrelevant, but the Departments believe it could be confusing. The Departments further note that the language in the two notices is verbatim with the exception of the final two sentences (which must not appear in notices provided with short-term, limited-duration insurance policies with a coverage start date on or after January 1, 2019). Therefore, the Departments believe any burden associated with the two notices applying to different periods are outweighed by the benefits of mitigating the potential for consumer confusion that could result from maintaining the last two sentences in the notice, when provided for policies with an effective date on or after January 1, 2019.

With respect to additional flexibility to add language to the notices, the Departments have clarified as part of the final regulations that states may require additional language to be included in the notices, as discussed elsewhere in this rule. In addition, there is no prohibition on issuers including additional language in their notices, as long as the additional language accurately describes the coverage.

Many commenters suggested specific changes to the content of the notices. Some commenters suggested expanding the notice to include details such as which benefits are not covered by the plan, whether preexisting conditions are covered, which PPACA protections will not be applicable, and more clearly state that loss of short-term, limited-duration insurance will not trigger a special enrollment period in the individual market. Several commenters stated that the notice should not only distinguish short-term, limited-duration insurance from available individual market plans, but should also distinguish the former from excepted benefits coverage. Some commenters suggested making the notice available in several languages. One commenter stated that the notice should illustrate how certain conditions would be covered. Several commenters stated that the notice should not be in capital letters. A few commenters stated that the notice should inform consumers that if they choose to purchase short-term, limited-duration insurance following expiration of the policy, they will be underwritten again, while another commenter stated that the notice should state that, even if the consumer passes re-underwriting, he may not be covered for medical conditions that the previous policy covered. A few commenters stated that the notice should indicate that purchasers of short-term, limited-duration insurance cannot qualify for PTCs (although some purchasers of qualified health plans sold on the Exchange can). One commenter stated that the notice should say that the policy "does not comply," as well as "is not required to comply," with PPACA requirements. One commenter stated that the notice should have a CAUTION heading, be in bullet form, be written in dark-color type, be literacy-tested to a 6th grade reading level, and have the MEC language listed first. One commenter stated that the notice should appear on the first page of the policy, rather than be displayed "prominently." One commenter stated that the

statement that short-term, limited-duration insurance may not comply with PPACA and may require additional payment with your taxes should be removed. One commenter noted that in addition to PPACA, short-term, limited-duration insurance is also exempt from other specific federal laws and that should be included in the notice as well. One other commenter recommended that the notice include a link to the applicable state-based Exchange website or *HealthCare.gov*.

The Departments agree with some of the commenters who suggested providing additional specificity in the notice. Therefore, the notice in the final rule has been revised to add language to make consumers aware of potential exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). The notice in the final rule also contains new language informing consumers that the policy might have lifetime and/or annual dollar limits on health benefits. The Departments did not incorporate the other additional language suggested by other commenters. The Departments believe the language added in this final rule provides important new information to consumers, without lengthening the notice to such an extent that would make it cumbersome to read, or cause consumers to not read it at all. The Departments are also cognizant of the burdens and costs on issuers that would be associated with a longer notice. However, states may require additional language in the notice, consistent with their authority to regulate short-term, limited-duration insurance. The Departments also agree with the commenters who suggested that the notice not be in all capital letters, as the Departments believe the notice will be more readable in sentence case.[43] Therefore, the notice in the final rule is in sentence case.

Given the varying demographics of different states, the Departments disagree with the comment that this final rule should require the notice to be available in several languages. Although the Departments believe it is important for the disclosure notice to be useful and informative to individuals who are most literate in a language other than English, the Departments decline in this rule to require that the notice be provided in additional languages. States as primary regulators of short-term, limited-duration insurance can impose additional requirements as may be necessary to meet local needs. The Departments disagree with the comment that the notice have a CAUTION heading, should be in bullet form, should be written in dark-color type, be literacy-tested to a 6th grade reading level, and should have the MEC language listed first. The Departments believe the form of this notice should be in straight text, which is the same form of most documents that individuals are accustomed to reading. The Departments also believe that a CAUTION heading might inappropriately bias the reader against short-term, limited-duration insurance; the Departments instead believe the notice should assist the consumer in making an informed choice about the type of coverage that is most appropriate for him or her. The Departments disagree with the comment that the MEC language should appear first in the notice. Although that language is important, the Departments believe most consumers would find the language that appears before the MEC language in the final notice to be more significant when deciding whether short-term, limited-duration insurance is the most appropriate type of coverage for their personal needs.

In addition, the Departments believe the language in the notice in the proposed rule stating that "This coverage is not required to comply with federal requirements for health insurance" could be interpreted too broadly, as meaning that the issuer of such coverage is not required to comply with certain other federal requirements not related to health insurance market rules that apply generally to issuers as well as other entities. Therefore, the Departments revise that clause in the notice in this final rule to read: "This coverage is not required to comply with certain federal market requirements for health insurance." In this final rule, the disclosure now reads as follows, with the first, second and third sentences differing from the proposal:

> This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

Importantly, the Departments note that we do not have evidence that erm, limited-duration insurance has not historically covered or is unlikely to cover hospitalization and emergency services. These benefits are included in the notice, however, due to an abundance of caution. Several commenters stated that, in order to meet the definition of short-term, limited-duration insurance, the issuer should be required to provide information through other means in addition to the notice. One commenter stated that, in addition to the notice, to satisfy the definition of short-term, limited-duration insurance, issuers should be required to include a plain-language explanation of the general limits of such insurance in the application, and that the application should have a signature line indicating that the consumer received and understood it. Several commenters stated that the notice should require the purchaser to initial several discrete statements about the limitations of the policy at the time of application. Several commenters stated that the Summary of Benefits and Coverage (SBC) requirement, as set forth in section 2715 of the PHS Act, should apply to short-term, limited-duration insurance. One commenter stated that the term "short-term, limited-duration insurance" should display prominently in the footer on every page of the contract, and in any application, sales, and marketing materials, and the outline of coverage should include a "warning" that this is temporary coverage that provides limited benefits. Several commenters stated that the statement in the notice should also appear in marketing materials. One commenter stated that the notice should be read out loud to any prospective purchaser, particularly those with limited English proficiency. One commenter stated that, in addition to providing the notice, short-term, limited-duration issuers should be required to name their policies in such a way as to distinguish them from individual health insurance coverage, maybe by inserting the word "Limited" as part of the name of the policy. Several commenters stated that the notice should be accompanied by a list of network providers.

[43] *See also*, for example, Bryan A. Garner, *What's Wrong With Initial-Caps Point Headings, https://bit.ly/2uNHtNL* (over use of capital letters may mean that "readers will probably skip over what you're trying to make sink in.")

The Departments believe that the requirements relating to both the content and delivery of the notice as set forth in this final rule strike the appropriate balance to help each consumer make an informed choice about the type of coverage that is most appropriate for him or her, while not being overly burdensome to issuers of short-term, limited-duration insurance or inappropriately biasing the reader against short-term, limited-duration insurance. The Departments therefore decline to adopt these suggestions by commenters. However, as previously noted, states may specify additional methods and forms of disclosure, as well as mandate additional disclosure requirements that issuers of short-term, limited-duration insurance must comply with, consistent with their authority to regulate such coverage. Because short-term, limited-duration insurance is not individual health insurance coverage under the PHS Act, it is not subject to the SBC requirements established under section 2715 of the PHS Act.

Finally, the Departments note that to the extent an issuer of short-term, limited-duration insurance provides a contract or application materials in connection with extension or renewal of a short-term, limited-duration policy, the notice must be displayed prominently in any such materials, just as it must be displayed prominently in the contract and in any materials provided in connection with enrollment in such coverage.

Short-Term, Limited-Duration Insurance as Student Health Insurance Coverage

Some commenters asked whether short-term, limited-duration insurance may be sold as "student health insurance coverage" within the meaning of HHS regulations. It may not.

"Student health insurance coverage" is defined in HHS regulations at 45 CFR 147.145(a), which provides that "student health insurance coverage" is a type of individual health insurance coverage. Thus, "student health insurance coverage" under the definition of "student health insurance coverage" must satisfy the PHS Act requirements for individual health insurance coverage, except for those specified in 45 CFR 147.145(b). Accordingly, short-term, limited-duration insurance cannot be "student health insurance coverage" because it is by definition not individual health insurance coverage. However, to the extent permitted by state law, an issuer may sell short-term, limited-duration insurance to individual students in institutions of higher education (or to individual students in boarding or other pre-higher-education institutions). Some higher education institutions may require their students to either purchase "student health insurance coverage," or a type of coverage other than short-term, limited-duration insurance.

Short-Term, Limited-Duration Insurance and Minimum Essential Coverage

A few commenters asked whether, under the final rule, short-term, limited-duration insurance would be considered MEC. One commenter suggested that the Departments provide a special enrollment period to purchase individual health insurance coverage for individuals who lose short-term, limited-duration insurance coverage outside of the individual market open enrollment period, similar to how individuals who lose MEC are currently provided a special enrollment period.

Short-term, limited-duration insurance is not individual health insurance coverage, nor is it MEC. This rule does not recognize short-term, limited-duration insurance as MEC. The Departments further note that the reduction of the individual shared responsibility payment to $0 beginning with coverage months after December 31, 2018, mitigates the need to designate short-term, limited-duration insurance as MEC, given that individuals who do not have MEC during any such coverage months, including individuals who have short-term, limited-duration coverage, will not be subject to the individual shared responsibility payment. Additionally, this rule does not create a special enrollment period to enroll in individual health insurance coverage for individuals whose short-term, limited-duration insurance has ended. The disclosure notice puts purchasers of short-term, limited-duration insurance on notice that no such special enrollment period is available. The Departments acknowledge that the loss of eligibility for short-term, limited-duration insurance creates a special enrollment opportunity to enroll in a group health plan (as opposed to individual health insurance coverage), either insured or self-insured.[44]

Other Federal and State Requirements

Several commenters were in favor of imposing various additional federal requirements on short-term, limited-duration insurance that were not included in the proposed rule. These included requiring additional training for agents and brokers who sell such insurance, minimum federal standards such as a minimum range of benefits to be offered equally in rural and urban areas, basing premiums on statewide markets, coverage of preexisting conditions and preventive services and network adequacy standards, federal regulation and oversight of short-term, limited-duration insurance policies sold through group trusts and associations, and requirements for websites marketing both short-term, limited-duration insurance and individual health insurance coverage.

For purposes of establishing federal standards for short-term, limited-duration insurance, the Departments believe that setting the initial contract term to less than 12 months, a maximum duration for a policy (including renewals or extension under the same insurance contract) of 36 months, and a notice requirement, as set forth in this final rule, are the only necessary federal standards for short-term, limited-duration insurance. In recognition of the states' important, traditional role in regulating short-term, limited-duration insurance, the Departments decline to adopt any additional federal standards such as those suggested by the commenters. As discussed elsewhere in this final rule, states generally remain free to adopt these suggested standards, or other standards, as they see fit.

In response to the Departments' solicitation of comments on any regulations or other guidance or policy that limits issuers' flexibility in designing short-term, limited-duration insurance or poses barriers to entry into the short-term, limited-duration insurance market, a few commenters mentioned section 1557 of PPACA as such a limitation. One commenter observed that the lack of standardized regulation of short-term, limited-duration insurance across state lines causes barriers to entry, and suggested the Departments encourage state insurance departments to participate in an interstate compact to create standard regulations that result in one policy form filing and approval that is effective in many states.

Section 1557 of PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. This provision is administered by the HHS Office for Civil Rights, and it is beyond the scope of this rule to address the impact of section 1557 of PPACA on short-term, limited-duration insurance. With respect to the comment that state insurance departments should participate in an interstate compact to create standard regulations that result in

[44] *See* 26 CFR 54.9801–6, 29 CFR 2590.701–6, 45 CFR 146.117.

one policy form filing and approval that is effective in many states, the Departments did not propose and are not adopting such federal standards and generally defer to state insurance departments on that issue.

Effective Date and Applicability Date

The Departments proposed that this rule, if finalized, would be effective 60 days after publication of the final rule in the **Federal Register**. With respect to the applicability date, the Departments proposed that insurance policies sold on or after the 60th day following publication of the final rule, if finalized, would have to meet the definition of short-term, limited-duration insurance in the final rule in order to be considered such insurance. The Departments also proposed that group health plans and group health insurance issuers, to the extent they must distinguish between short-term, limited-duration insurance and individual health insurance coverage, must apply the definition of short-term, limited-duration insurance in the final rule as of the 60th day following publication of the final rule. The current regulations specify the applicability date for the definition of short-term, limited-duration insurance at 26 CFR 54.9833–1, 29 CFR 2590.736, 45 CFR 146.125, and 45 CFR 148.102. Therefore, the Departments proposed conforming amendments to those rules as part of this rulemaking.

The Departments also proposed a technical update in 26 CFR 54.9833–1, 29 CFR 2590.736, and 45 CFR 146.125 to delete the reference to the applicability date for amendments to 26 CFR 54.9831–1(c)(5)(i)(C), 29 CFR 2590.732(c)(5)(i)(C), and 45 CFR 146.145(c)(5)(i)(C) (regarding supplemental coverage excepted benefits).[45] Given that the applicability date for the amendments to those sections has passed, the Departments explained that it is no longer necessary to mention the "future" applicability date.[46] HHS similarly proposed to amend 45 CFR 148.102 to remove the reference to the applicability date for amendments to 45 CFR 148.220(b)(7) (regarding supplemental coverage excepted benefits).[47]

Some commenters supported the proposed effective and applicability date, suggesting that the rule should be effective and applicable as soon as possible, while others stated that the rule should be applicable as of January 1, 2019. Others stated that it should be applicable January 1, 2020, to allow issuers time to plan and prepare new plan designs and regulatory filings and to allow states the chance to enact any legislation or promulgate regulations they felt necessary. One commenter asserted that if the rule were to become effective in 2018, it would disrupt the markets for 2018 and 2019 without providing a fair opportunity for health insurance issuers of individual market plans to adjust their rates to account for the potential impact on the individual market risk pool. This commenter also stated that a delayed effective date would allow states time to educate the public. Some states and the National Association of Insurance Commissioners (NAIC) expressed concerns about the timing of this rule, noting that some states may want to modify existing laws and regulations and asked the Departments to give such states time to review their rules and seek statutory or regulatory changes. These states asked for flexibility in overseeing short-term, limited-duration insurance plans according to market-specific needs, including the ability to postpone or otherwise delay the effective date to review existing state requirements to facilitate a smooth transition and educate the public about this coverage option. Another commenter asked for an effective date that would allow issuers to begin selling short-term, limited-duration insurance, as defined in this final rule, in 2019, stressing the collapse of its individual market. One commenter stated that, given that individual health insurance issuers have set their 2018 rates assuming that short-term, limited-duration insurance is limited to less than 3 months, a change in the rule at this point would violate serious reliance interests.

The Departments understand that an applicability date of 60 days following publication of this final rule might cause challenges for some states and issuers as they move to adopt, enforce, and comply with the final rule. However, as stated elsewhere in this final rule, the Departments believe there is a critical need to expand access to health coverage choices in addition to individual health insurance coverage, which, as stated above, may not be the most appropriate or affordable policies for many individuals. The Departments believe that a uniform federal standard of less than 12 months for the initial contract term, with renewals or extensions permitted for a maximum duration of up to 36 months under a policy, and with the notice set forth in the final rule, is the appropriate federal standard for the reasons stated earlier, and must be applicable as soon as possible. Therefore, this final rule provides that the new definition of short-term, limited-duration insurance applies to insurance policies sold on or after October 2, 2018. This effective and applicability date, which is 60 days after the date this final rule was published in the **Federal Register**, is the effective and applicability date that was proposed in the proposed rule. The Departments realize that some states may wish to retain the less-than-3-month duration standard that was set forth in the October 2016 final rule, or some other standard that is narrower than the federal definition but for whom it might be difficult to enact legislation, or promulgate a regulation before the final rules goes into effect. Thus, the Departments reiterate that included in states' ability and authority to define and regulate short-term, limited-duration insurance, is the ability and authority to define and regulate such coverage in such a way as to impose a shorter (but not longer) maximum initial contract term and a shorter (but not longer) maximum duration for a policy than those included in this final rule. In addition, issuers of short-term, limited-duration insurance must comply with the notice requirement in this final rule, with respect to policies sold on or after October 2, 2018, with states having flexibility to require additional disclosures.

Group health plans, to the extent they must distinguish between short-term, limited-duration insurance and individual health insurance coverage for purposes of the federal requirements under the PHS Act, may apply the definition of short-term, limited-duration insurance contained in the final rule, as of October 2, 2018. The Departments believe this approach might substantially reduce burden for group health plan sponsors, particularly sponsors of large group health plans that operate in multiple states, as the Departments believe it could be burdensome for sponsors of such plans to have to familiarize themselves with the definition of short-term, limited-duration insurance that applies in each state in which the group health plan operates. However, to the extent an insurance contract is subject to state law that requires short-term, limited-duration insurance to have a maximum

[45] As explained in the proposed rule, the reference in current regulations at 45 CFR 146.125 to the applicability date of 45 CFR 146.145(c)(5)(i)(C) was a drafting error. It was intended to be a reference to 45 CFR 146.145(b)(5)(i)(C).

[46] The applicability date for these amendments (policy years and plan years beginning on or after January 1, 2017) remains unchanged.

[47] The applicability date for these amendments (policy years beginning on or after January 1, 2017) remains unchanged.

initial contract term and/or total duration of coverage that is shorter than the maximum periods under the definition of short-term, limited insurance in this final rule, and that requires the notice specified in that definition, a plan or a health insurance issuer may, or, if permitted or required by applicable state insurance law, must, as applicable, determine whether a given insurance contract is individual health insurance coverage or is short-term, limited-duration insurance by applying that state law to the coverage.

The Departments received no comments on the proposed conforming amendments and technical updates with respect to the applicability date, and are finalizing them in this final rule.

III. Economic Impact and Paperwork Burden

A. Summary

This rule amends the definition of short-term, limited-duration insurance coverage so that the coverage has a maximum initial contract term of less than 12 months and a maximum duration (including the initial contract term and renewals and extensions of the same insurance contract) of no longer than 36 months. The final rule also requires a notice be included in the contract and any application materials provided in connection with enrollment in such coverage.

The Departments have examined the effects of this rule as required by Executive Order 13563 (76 FR 3821, January 18, 2011, Improving Regulation and Regulatory Review), Executive Order 12866 (58 FR 51735, September 30, 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 (January 30, 2017, Reducing Regulation and Controlling Regulatory Costs).

B. Executive Orders 12866 and 13563

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects (for example, $100 million or more in any 1 year), and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments anticipate that this regulatory action is likely to have economic impacts of $100 million or more in at least 1 year, and therefore meets the definition of a "significant rule" under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with this final rule. In accordance with the provisions of Executive Order 12866, this final rule was reviewed by OMB.

1. Need for Regulatory Action

This rule contains amendments to the definition of short-term, limited-duration insurance for purposes of the exclusion from the definition of individual health insurance coverage under the PHS Act. This regulatory action is taken in light of Executive Order 13813 directing the Departments to consider proposing regulations or revising guidance to expand the availability of short-term, limited-duration insurance, as well as continued feedback from stakeholders expressing concerns about the October 2016 final rule. While individuals who qualify for PTCs are largely insulated from significant premium increases, individuals who are not eligible for subsidies are harmed by increased premiums in the individual market and the lack of other, more affordable, alternative coverage options. This final rule aims to increase insurance options for individuals unable or unwilling to purchase available individual market plans and provide more flexibility to states to pursue innovative solutions to meet their market-specific needs.

2. Summary of Impacts

In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. The Departments believe the need for coverage options that are more affordable than individual health insurance coverage is critical, combined with the general need for more coverage options and choice. Therefore, the Departments believe that the benefits associated with this rule outweigh the costs.

TABLE 1—ACCOUNTING TABLE

Benefits:
Qualitative:
• Increased access to affordable health insurance for consumers unable or unwilling to purchase available individual market plans, potentially decreasing the number of uninsured individuals and resulting in improved health outcomes for these individuals.
• Increased choice at lower cost and increased financial protection (for consumers who are currently uninsured or face extremely high premiums and deductibles for PPACA coverage) from catastrophic health care expenses for consumers purchasing short-term, limited-duration insurance.
• Potentially broader access to health care providers compared to available individual market plans for some consumers.
• Increased profits for issuers and brokers of short-term, limited-duration insurance.
• Economic efficiency gains from people buying unsubsidized coverage and minimizing overinsurance.

TABLE 1—ACCOUNTING TABLE—Continued

Costs:
Qualitative: • Reduced access to some services and providers for some consumers who switch from available individual market plans and possibly reduced choice for individuals remaining in the individual market risk pools. • Potential increase in out-of-pocket costs for some consumers, possibly leading to financial hardship.
Transfers:
Qualitative: • Transfer from taxpayers (via the Federal government) to enrollees in individual market plans in the form of increased PTC payments. • Potentially higher premiums for some consumers remaining in the individual market as healthier than average individuals choose short-term, limited-duration insurance to a greater degree. • Tax liability for consumers who replace available individual market plans and will thus no longer maintain minimum essential coverage in 2018. • Potential increase in uncompensated care by hospitals.

Short-term, limited-duration insurance represents a small fraction of the health insurance market. Based on data from the NAIC, in 2016, before the October 2016 final rule became effective, total premiums earned for policies designated short-term, limited-duration by carriers were approximately $146 million for approximately 1,279,500 member months and with approximately 160,600 covered lives at the end of the year. During the same period, total premiums for individual market (comprehensive major medical) coverage were approximately $63.25 billion for approximately 175,689,900 member months with approximately 13.6 million covered lives at the end of the year.[48] One commenter stated, however, that the actual enrollment in short-term, limited-duration insurance was close to 500,000 covered lives in December 2016, once association based sales were taken into account. Another commenter cited a report[49] stating that enrollment in such coverage may be closer to one million. Based on data from the NAIC, in 2017, total premiums earned for policies designated short-term, limited-duration by carriers were approximately $151 million for approximately 1,053,082 member months and with approximately 122,483 covered lives at the end of the year.[50] While sales of short-term, limited-duration insurance declined after the October 2016 final rule was finalized, the sales of such coverage were increasing prior to the issuance of that rule. In part because under the October 2016 rule short-term, limited-duration plans may be offered only for periods of less than three months, fixed administrative costs for issuers, including underwriting, are likely to be high relative to premiums. In addition, the transactions costs of obtaining plans are high for consumers, relative to benefits claimed. Allowing plans to be sold for a longer period of time is expected to reduce these costs, making short-term, limited-duration plans more attractive for issuers and consumers. Given this and the trend we observed prior to issuance of the October 2016 rule, the Departments expect more issuers to offer a greater variety of short-term, limited-duration plans, and more consumers to purchase such plans, as a result of this rule.[51]

a. Benefits

This rule will benefit individuals who have been harmed by the increasing premiums, deductibles and cost-sharing associated with individual market plans and by limited choices. This rule empowers consumers to purchase the benefits they want and reduce overinsurance. Short-term, limited-duration insurance is likely to represent more efficient amounts of coverage since it lacks distortionary price controls and regulation that can greatly separate price from value and lead some people to overinsure and others to underinsure.

Lengthening the term of short-term, limited-duration plans will help reduce the fraction of the population that is uninsured by giving the uninsured a greater variety of plan choices. Similarly this rule also offers additional choice to persons who would otherwise be limited to the products offered on their local Exchange. By reducing the per-month transactions and administrative costs on such plans, this rule confers an economic benefit to its members because the insurance market passes on some or all of the cost savings as premium savings. This rule also helps the economic burden of PPACA to be shared more equitably by shifting some of the premium costs to general revenue from individual-market customers who are induced to purchase short-term, limited-duration plans rather than Exchange plans.

Consumers who purchase short-term, limited-duration insurance for longer periods than currently permitted will benefit from increased insurance options at lower premiums, as the average monthly premium for an individual in the fourth quarter of 2016 for a short-term, limited-duration policy was approximately $124 compared to $393 for an unsubsidized individual market plan—a premium savings of 70 percent.[52] This disparity may be wider given that unsubsidized premiums significantly increased from 2016 to 2018. A recent study concluded that the least expensive short-term, limited-duration insurance policy often costs 20 percent or less of the premium for the lowest-cost individual market bronze plan in the area.[53] While there is a significant difference in the premiums for short-term, limited-duration

[48] National Association of Insurance Commissioners, "2016 Accident and Health Policy Experience Report", July 2017. Available at *http://www.naic.org/prod_serv/AHP-LR-17.pdf.*

[49] Reed Abelson, "Without Obamacare Mandate, 'You Open the Floodgates' for Skimpy Health Plans", the New York Times, November 30, 2017. Available at *https://www.nytimes.com/2017/11/30/health/health-insurance-obamacare-mandate.html.*

[50] National Association of Insurance Commissioners, "2017 Accident and Health Policy Report", July 2018. Available at *https://naic.org/prod_serv/AHP-LR-18.pdf.*

[51] Other analysts also expect issuers to offer a greater variety of short-term limited-duration plans as a result of this rule. *See* Congressional Budget Office, "Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018 to 2028," May 23, 2018. Available at *http://cbo.gov/publication/53826.*

[52] Michelle Andrews, "Sales Of Short-Term Insurance Plans Could Surge If Health Law Is Relaxed", NPR, January 31, 2017. Available at *http://www.npr.org/sections/health-shots/2017/01/31/512518502/sales-of-short-term-insurance-plans-could-surge-if-health-law-is-relaxed.*

[53] Karen Pollitz, Michelle Long, Ashley Semanskee, and Rabah Kamal, "Understanding Short-Term Limited Duration Health Insurance", Kaiser Family Foundation, April 23, 2018. Available at *https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/.*

insurance and unsubsidized individual market plans, individuals qualifying for PTCs may not find the difference in premiums as appealing, as the difference in their out-of-pocket premium costs is likely relatively small. A recent study estimated that in 2016 the consumer portion of the premium, after the tax credit, for a 40 year old non-smoker making $30,000 per year ranged from $163 to $206 per month in most of the country.[54] However, the premium cost for a 40 year old non-smoker making $30,000, before accounting for any tax credit, ranged from $183 to $719 per month depending on location.[55] This rule will provide an affordable alternative to individuals who do not qualify for PTCs and have been harmed by rising premiums in the individual market. This final rule will also benefit individuals who need coverage for longer periods, such as those who need more than 3 months to find new employment, or who find available individual market plans to be unaffordable. Individuals who purchase short-term, limited-duration insurance as opposed to being uninsured will potentially experience improved health outcomes and have greater financial protection from catastrophic health care expenses. Individuals purchasing short-term, limited-duration policies may obtain broader access to health care providers compared to what they would obtain through individual market plans that have narrow provider networks.[56]

Issuers of short-term, limited-duration insurance will benefit from higher enrollment. They are likely to experience an increase in premium revenues and profits because such policies can be priced in an actuarially fair manner (by which the Departments mean the policies are priced so that the premium paid by an individual reflects the risks associated with insuring the particular individual or individuals covered by that policy) and issuers have experience pricing in this manner. In addition, the fixed costs of issuing plans will be reduced relative to premiums as issuers will not need to reissue plans every 3 months in order to cover consumers for a year or more.

In response to the Departments' request for comments on the benefits of having short-term, limited-duration insurance, many commenters stated that short-term, limited-duration insurance has served a critical role in providing temporary limited health coverage to individuals who would otherwise go uninsured. Some commenters also stated that the proposed changes would allow potential purchasers of short-term, limited-duration insurance, especially those who find individual market plans to be unaffordable, to obtain the coverage they want (and exclude services they do not want) at a more affordable price for a longer period of time. Other benefits commenters stated would flow from extending the maximum duration for short-term, limited-duration insurance include the facts that deductibles will not be reset every 3 months and that health conditions that develop during this coverage period will continue to be covered for a longer period of time. Commenters also stated that increasing the length of coverage would expand access to affordable coverage options for those who otherwise would lose coverage and could not pass underwriting and would not qualify for a special enrollment period because they would not be forced to go without coverage until the next open enrollment period. One commenter cited Bureau of Labor Statistics data that the average length of unemployment in the United States (U.S.) is 24.1 weeks, or about 5.5 months, as of March 2018; further stating that in 20.3 percent of cases the period of unemployment lasts 27 weeks or more, which means that 6 months is often not long enough to secure gainful employment.[57] Therefore, limiting the duration of short-term, limited-duration insurance policies to 3 months, or even 6 months, harms those Americans who find themselves unemployed for the average length of time or longer.

The Departments agree with the commenters that increasing the maximum duration of a short-term, limited-duration insurance policy will benefit consumers who have been most harmed by PPACA (for example, those who cannot afford or do not want individual health insurance coverage) or who want to purchase such coverage for longer than 3 months; it also will provide states with additional flexibility to pursue innovative approaches to expand access to coverage options in addition to individual health insurance coverage. The final rule increases the maximum duration of the initial contract term, under the federal definition, to less than 12 months and permits such policies to be renewed or extended such that the maximum duration of a policy, including the initial contract term specified in the contract and renewals and extensions, is no longer than 36 months.

One commenter asserted that short-term, limited-duration insurance plans typically provide coverage for all major benefits such as: Doctor and specialist visits, preventive/wellness care, emergency care, x-rays, lab tests, transplants, intensive care, and hospitalization. In addition, the commenter noted, short-term, limited-duration insurance policies can include benefits for mental health disorders, substance abuse, physical therapy, speech therapy, home health care, ambulance, and other covered medical expenses. The commenter also claimed that these policies generally provide coverage for prescription drugs that are administered by a doctor in a setting covered by the policy and there is typically outpatient prescription coverage for drugs that require a written prescription and are necessary to treat a condition covered by the policy.

One commenter stated that a key feature of typical short-term, limited-duration insurance is that the plan benefits are paid for covered expenses incurred from any provider in the U.S. and there is no referral required if a member would like to see a specialist. According to the commenter, members have the added benefit of receiving discounted network rates if they choose to use an in-network provider.

The Departments agree that short-term, limited-duration insurance could be a desirable and affordable option for many consumers. The Departments are therefore finalizing a definition in this final rule to remove federal barriers that inhibit consumer access to additional, more affordable coverage options while, at the same time, distinguishing it from individual market health insurance coverage. States remain free to regulate these products as set forth elsewhere in this final rule.

Some commenters stated that the potential risks of high copayments and severely limited health coverage associated with short-term, limited-duration insurance significantly outweigh the cost savings from enrollment in such plans. A commenter

[54] Cynthia Cox, Selena Gonzales, Rabah Kamal, Gary Claxton and Larry Levitt, "Analysis of 2016 Premium Changes in the Affordable Care Act's Health Insurance Marketplaces", Kaiser Family Foundation, October 26, 2015. Available at *https://www.kff.org/health-reform/fact-sheet/analysis-of-2016-premium-changes-in-the-affordable-care-acts-health-insurance-marketplaces/*.

[55] Id.

[56] Anna Wilde Mathews, "Sales of Short-Term Health Policies Surge: Some consumers opt for limited coverage, saying it is cheaper than conventional plans", Wall Street Journal, April 10, 2016. Available at *https://www.wsj.com/articles/sales-of-short-term-health-policies-surge-1460328539*. The ability of short-term, limited-duration plans to provide broad provider networks has been touted by some in the insurance community.

[57] The Departments note that the average duration of unemployment as reported by the Bureau of Labor Statistics is an arithmetic mean based on observed incomplete spells of unemployment. The actual average duration of completed spells of unemployment could be longer or shorter.

stated that the analysis in the proposed rule does not sufficiently explain how the benefits of expanding short-term, limited-duration insurance could possibly outweigh the disruption and consumer harm caused by the proposed changes.

Some commenters stated that some of the benefits are mischaracterized; for example, people with short-term, limited-duration insurance don't have broader access to health care providers, when many benefits and health conditions are entirely excluded from short-term, limited-duration plans. Commenters suggested that other purported benefits of the proposed rule (such as lower premiums for some healthier people) would be erased by its harmful impacts (higher premiums in the individual market as a whole).

One commenter stated that potential increases in access to health care and choice are "illusory". The commenter provided an example where an issuer of short-term, limited-duration insurance claims not to restrict enrollees to a network, but in reality pays claims up to a fixed percentage of Medicare reimbursement rates, leaving enrollees responsible for any amounts above that threshold. The commenter explained that this essentially is equivalent to being enrolled in a PPO plan with an empty network that leaves enrollees faced with high out-of-pocket expenses after receiving care.

With regard to the claim that short-term, limited-duration insurance can offer broader network coverage, a commenter expressed concerns that the Departments relied on promotional material provided by an issuer. Another commenter stated that the coverage may have a very limited network of providers and may not provide any coverage for out-of-network providers, while others stated that the exclusion of services effectively limits the actual networks by excluding providers, and this could particularly affect rural areas.

One commenter stated that while premiums for short-term, limited-duration insurance policies will likely be lower relative to individual market plans, using premiums as the sole measure of a benefit to consumers provides an incomplete analysis. This commenter noted that short-term, limited-duration insurance policies fail to provide comprehensive coverage and thus expose consumers who have a serious medical condition, such as cancer, to significant out-of-pocket costs. The commenter also suggested that the analysis fails to take into account that due to underwriting, premiums for short-term, limited-duration insurance policies can expose even relatively healthy older individuals to significant premiums, and could also result in individuals with preexisting conditions being denied coverage or charged significantly higher premiums due to their health conditions.

A few commenters stated that short-term, limited-duration insurance plans should also not be compared with being uninsured, rather they should be compared to individual market plans. Many commenters stated that the Departments should look at the benefits to all consumers and not just young and healthy individuals.

This rule will benefit individuals who have been harmed by the increasing premiums, deductibles and cost sharing associated with individual market plans and limited choices—both in terms of coverage options and in terms of narrowing provider networks. The Departments' judgment is that individuals are in the best position to evaluate the tradeoffs between the benefits and costs of various coverage alternatives. This rule empowers consumers to make decisions on the benefits they want and reduce the potential for overinsurance and underinsurance while expanding access to more affordable coverage options. As acknowledged previously, short-term, limited-duration insurance may not be the most suitable coverage for everyone. Individuals who desire comprehensive coverage subject to PPACA rules will continue to have the option of purchasing individual market health insurance coverage on a guaranteed available and guaranteed renewal basis. Also, individuals who receive PTCs generally will not experience an increase in out-of-pocket costs for premiums if they continue to purchase Exchange coverage. However, this final rule provides another choice in addition to individual health insurance coverage for consumers to consider, based on their own personal circumstances and needs. In many cases, short-term, limited-duration insurance will provide a more desirable option for individuals, especially those who would otherwise be uninsured, those not eligible for PTCs, those who have lost their employment and are unable to afford individual market coverage, and those with objections to purchasing coverage of certain services or products that are mandated to be covered by PPACA. In that regard, the Departments believe it is appropriate to compare having short-term, limited-duration insurance to both being uninsured as well as having individual health insurance coverage. Uninsured individuals who purchase short-term, limited-duration insurance will experience an increase in financial protection and may gain greater access to certain health care providers. Moreover, individual market plan networks may also be quite restrictive, and short-term, limited-duration plan networks may very well cover a broader array of providers. For most individuals who switch to short-term, limited-duration insurance from individual market plans, lower premiums will provide the biggest benefit. Short-term, limited-duration insurance may also provide consumers with benefits that are more tailored to their individual or familial needs or circumstances. Commenters have valid concerns about the potential for misleading information about provider networks, which can also be a concern with individual market plans,[58] and we generally defer to the states to address such concerns as part of their regulation and oversight of health insurance.

Many commenters stated that issuers and brokers will receive higher profits and commissions for these plans, as issuers have made moves to reduce broker commissions for individual market plans. One commenter mentioned that according to available data from the NAIC, in 2015 the industry-wide average MLR for "Short-Term Medical" was 69.76 percent, with smaller companies falling below 50 percent MLR for the vast majority of the total market share. The commenter stated that health insurance products with an MLR at or below 50 percent raise a red flag because when a majority of the company's revenue is not spent on medical services, consumer health becomes a secondary part of its business.

The Departments acknowledge that issuers and brokers of short-term, limited-duration insurance will benefit from the changes finalized in this rule to varying degrees depending on state regulations of short-term, limited-duration insurance. Short-term, limited duration insurance is not subject to the federal MLR standards under section 2718 of the PHS Act and this final rule does not establish a federal MLR threshold for short-term, limited-duration insurance. There is also a large variation in the reported MLR for short-term, limited-duration insurance. Average MLR for short-term, limited-duration coverage was approximately 67 percent in 2016.[59] For the top 10 issuers

[58] Chad Terhune, "Top insurers overstated doctor networks, California regulators charge", Los Angeles Times, November 18, 2014. Available at *http://www.latimes.com/business/la-fi-obamacare-network-probe-20141119-story.html.*

[59] National Association of Insurance Commissioners, "2016 Accident and Health Policy

that accounted for almost 94 percent of the national short-term, limited-duration insurance market their MLRs ranged from 47.46 percent to 219.61 percent in 2016.[60] MLR may be of limited utility in evaluating the efficiency of insurance coverage and may result in higher medical costs and premiums, less innovation in plan design, less consumer choice, and increased market concentration.[61] As previously mentioned, the majority of short-term, limited-duration insurance policies were sold as transitional coverage in 2016, and the duration of such policies typically was less than 3 months. Increased administrative costs due to underwriting and the short duration may also explain the lower-end reported MLRs for short-term, limited-duration insurance policies in 2016. As the short-term, limited-duration insurance market grows, the Departments anticipate that in the long term more issuers will sell such coverage, increasing competition and limiting excessive profits.

b. Costs and Transfers

Short-term, limited-duration insurance policies are unlikely to include all the requirements applicable to individual market plans, such as the preexisting condition exclusion prohibition, coverage of essential health benefits without annual or lifetime dollar limits, preventive care, maternity and prescription drug coverage, rating restrictions, and guaranteed renewability. Therefore, consumers who switch to such policies from individual market plans will experience loss of third-party payments for some services and providers and potentially an increase in out-of-pocket expenditures related to such excluded services, as well as an exclusion of benefits that in many cases consumers do not believe are worth their cost (which could be one reason why many consumers, possibly even those receiving subsidies for Exchange plans, may switch to short-term, limited-duration policies rather than remain in individual market plans). Depending on state regulation, issuer plan design, and whether consumers decline to purchase a separate renewal guarantee product, consumers who purchase short-term, limited-duration insurance policies and then develop chronic conditions may face financial hardship as a result, until they are able to enroll in individual market plans that will provide coverage for such conditions.

Since short-term, limited-duration insurance is not MEC, any individual enrolled in short-term, limited-duration coverage that lasts 3 months or longer in 2018 will potentially incur a tax liability for not having MEC during that year. Starting in 2019, the individual shared responsibility payment included in section 5000A of the Code is reduced to $0, as provided under Public Law 115–97, and thus no tax liability could accrue in that year and thereafter for not having MEC. However, the tax liability is not the sole consequence of not having MEC. Because short-term, limited-duration insurance does not qualify as MEC, those individuals who lose coverage in these plans may not qualify for a special enrollment period in the individual market and may face a period of time in which they have no medical coverage, and this will continue to be the case even after 2018. Purchasing a renewal guarantee, however, may eliminate the need for a special enrollment period.

The Departments requested and received many comments on the potential costs of the proposed changes. Many commenters pointed out the possible negative impacts and costs associated with the proposed changes, especially the effect on consumers' out-of-pocket costs. Many commenters stated that consumers considering purchasing short-term, limited-duration insurance policies are unlikely to know the limitations of the policies and the non-applicability of the numerous PPACA consumer protections to these policies. Many commenters also stated that the comprehensiveness of items and services covered by short-term, limited-duration insurance coverage can be misleading; individuals who are expected to need expensive services because of preexisting conditions would likely either have services for those conditions excluded from coverage or be denied coverage altogether. Thus, consumer expectations for short-term, limited-duration insurance policies may be significantly different from the realities of these policies. Commenters are concerned that the differences between short-term, limited-duration insurance policies and plans offered in individual and group markets may not be clear to consumers. As a result they may be exposed to excessive out-of-pocket costs.

This final rule requires issuers to provide a notice in application materials and the contract to alert consumers to the potential limitations of short-term, limited-duration insurance. States also have the flexibility to mandate the disclosure of additional information. This will help inform consumers about the limitations of short-term, limited-duration insurance and their choice of the coverage that best suit their needs. The notice language in the final rule provides more detail on the potential limitations of short-term, limited-duration insurance coverage than what was in the proposed rule to support informed coverage purchasing decisions by consumers, while those who are concerned about potential excessive out-of-pocket costs will continue to have the option to purchase individual market coverage that includes PPACA requirements.

Many commenters noted that short-term, limited-duration insurance often lacks consumer safeguards, generally excludes coverage for preexisting conditions, does not provide coverage for essential health benefits, often applies high deductibles and cost-sharing requirements, has lifetime and annual dollar caps on reimbursement for medical expenses, has no maximum limits on out-of-pocket costs, may be rescinded, and is generally available only for healthy consumers. As a result, consumers who purchase short-term, limited-duration insurance can experience significant financial hardship, especially if they require access to health care services not covered by their plan. These commenters noted that this is particularly problematic for people who have chronic or life-threatening conditions that require costly treatment, close monitoring and ongoing medication.

Commenters also stated that the potential risks of unreasonable copayments and severely limited health coverage associated with short-term, limited-duration insurance significantly outweigh the cost savings from enrollment in such plans. For example, according to one commenter, out-of-pocket costs for short-term, limited-duration insurance policies may be excessive in many markets: In Phoenix, AZ, the out-of-pocket cost-sharing limit for a 40-year-old male can be as high as $30,000 for a 3-month period. While another commenter pointed out that in Georgia, a plan had a 3-month out-of-pocket limit of $10,000, but did not include the deductible of $10,000, resulting in an effective 3-month out-of-pocket maximum of $20,000.

Some commenters are concerned about the lack of network adequacy requirements for short-term, limited-duration insurance. One commenter expressed concern that misleading claims related to provider networks

Experience Report", July 2017. Available at *http://www.naic.org/prod_serv/AHP-LR-17.pdf.*

[60] Id.

[61] Scott E. Harrington, "Medical Loss Ratio Regulation under the Affordable Care Act", Inquiry, 2013. Available at *https://www.jstor.org/stable/23480894.*

could result in consumers purchasing plans later finding that the provider networks may be non-existent in their specific market, as short-term, limited-duration plans are not subject to the network adequacy protections, leading to higher out-of-pocket costs.

Many commenters stated that these policies could subject patients to catastrophic medical bills and medical bankruptcy. For example, short-term, limited-duration insurance enrollees suffering acute health emergencies, debilitating injuries that lead to permanent disabilities, or the onset of chronic conditions could end up facing financial hardship until they can enroll in an individual (or group) market plan that provides the coverage they need. Many commenters shared their past experience with short-term, limited-duration insurance (as well as pre-PPACA individual market coverage) and provided numerous examples of how annual and lifetime dollar limits resulted in consumers being left responsible for large medical bills and high out-of-pocket costs and concluded that short-term, limited-duration insurance is not really an affordable alternative to available individual market plans. Many commenters stated that the proposed changes would reduce access to maternity care, treatment for illnesses such as cancer, cystic fibrosis, multiple sclerosis, arthritis, eating disorders, visions and hearing loss and mental health and substance use disorders. Many commenters shared personal stories of struggles with illnesses such as cancer and the financial and emotional toll of such illnesses. These commenters expressed deep fears that as a result of this rule, they would lose coverage because issuers would stop offering individual market plans or because those plans would become too expensive. These commenters expressed fear of becoming bankrupt and losing their lives because of reduced access to the necessary health care.

Commenters expressed concern that this would reverse the health coverage gains over the last few years, especially in minority communities and amongst women. One commenter stated that the design of short-term, limited-duration insurance in the proposed rule will discourage the pursuit of preventive services, so the public health will suffer.

This rule will benefit individuals who have been harmed by the increasing premiums, deductibles, and cost-sharing associated with individual market plans and by limited choices. Individual market premiums increased 105 percent from 2013 to 2017, in the 39 states using *Healthcare.gov* in 2017,[62] while the average monthly premium for the second-lowest cost silver plan for a 27-year-old increased by 37 percent from 2017 to 2018.[63] Individual market plans will continue to be available to individual consumers on a guaranteed availability basis and many individuals will have the opportunity to purchase the type of coverage that is most desirable and suitable for them and their families' health care and budget needs, unless states take actions to restrict the short-term, limited-duration market. Also, individuals who receive PTCs generally will not experience an increase in out-of-pocket costs for premiums. However, consumer expectations for individual market plans have often not been met due to high deductibles,[64] and short-term, limited-duration insurance provides an additional choice for individuals to consider, based on their own personal circumstances. In addition to dramatically higher premiums, high out-of-pocket costs have harmed many individual market plan enrollees, with deductibles that average nearly $6,000 a year for bronze single coverage and more than $12,000 a year for bronze family coverage in 2018 as well as more than $4,000 a year for silver single coverage and more than $8,000 a year for silver family coverage in 2018.[65] In addition, out-of-pocket maximums for individual market plans are only applicable to in-network care and thus actual out-of-pocket costs may be much higher for individuals who need to obtain care out of network. High deductibles may also be a deterrent to obtaining care for some individuals. In some cases, short-term, limited-duration insurance will provide a more desirable option for individuals and may be the only affordable alternative to being uninsured. To help consumers make informed coverage decisions, issuers of short-term, limited-duration insurance are required under this final rule to provide a notice to alert consumers to the potential limitations of the coverage. The Departments' judgment is that individuals are in the best position to evaluate the tradeoffs between lower premiums and limitations of short-term, limited-duration insurance. This rule empowers consumers to make decisions on the benefits they want and to reduce potential overinsurance and underinsurance. As discussed below, rather than increase the number of individuals who are uninsured the total number of individuals purchasing either individual market or short-term, limited-duration insurance coverage is expected to increase, perhaps significantly. Uninsured individuals who purchase short-term, limited-duration insurance will experience an increase in financial protection and potentially an increase in access to health care. As previously mentioned, individual market plan networks may also be quite restrictive, and short-term, limited-duration plan networks may very well cover a broader or superior set of providers. State regulators have also taken compliance action against misleading claims regarding benefits and provider networks, which should act as a disincentive to such practices. In response to the concern raised regarding bankruptcy, the rule makes clear that individuals are free to purchase separate products that may provide protection against the possibility of getting sick in the future and facing higher premiums as a result.

A few commenters also mentioned the potential increase in uncompensated care and the financial burdens that the increased use of short-term, limited-duration insurance could place on hospitals. Commenters stated that the proposed changes could have a devastating impact on hospital emergency rooms, since they are required to provide care regardless of coverage status or one's ability to pay. If more consumers enroll in short-term, limited-duration policies that do not cover treatments received in emergency departments, it will result in an increase in uncompensated care. In addition, the lack of coverage of essential health benefits may also lead to an increased reliance on emergency departments as consumers delay or do not seek primary care, exacerbating existing acute and chronic conditions. One commenter stated that this may also lead to increased boarding of mental health patients in emergency departments, where mental health patients presenting to an emergency department have an average stay of 18 hours, compared to an

[62] ASPE "Data Point—Individual Market Premium Changes: 2013–2017", May 23, 2017. Available at *https://aspe.hhs.gov/system/files/pdf/256751/IndividualMarketPremiumChanges.pdf.*

[63] ASPE "Health Plan Choice and Premiums in the 2018 Federal Health Insurance Exchange", October 30, 2017. Available at *https://aspe.hhs.gov/pdf-report/health-plan-choice-and-premiums-2018-federal-health-insurance-exchange.*

[64] Robert Pear, "Many Say High Deductibles Make Their Health Law Insurance All but Useless", The New York Times, November 14, 2015. Available at *https://www.nytimes.com/2015/11/15/us/politics/many-say-high-deductibles-make-their-health-law-insurance-all-but-useless.html.*

[65] HealthPocket, "Average Market Premiums Spike Across Obamacare Plans in 2018", October 27, 2017. Available at *https://www.healthpocket.com/healthcare-research/infostat/2018-obamacare-premiums-deductibles.*

average of only four hours for all emergency department patients.

The Departments acknowledge that if a short-term, limited-duration insurance policy excludes treatment in hospital emergency rooms, there is the possibility that there could be increases in uncompensated care provided by hospitals. However, the Departments have no reason to believe that all short-term, limited-duration insurance policies will exclude such coverage. The Departments note that individuals enrolled in individual market plans also frequently experience unexpected high out-of-pocket costs due to balance billing (charges arising when an insured individual receives care from an out-of-network provider, the balance bill being the difference between the total charges incurred and what the issuer ultimately pays), when obtaining care at emergency departments and when treating providers are not part of in-network hospitals.[66] Very few states have laws that protect consumers from this practice; 15 states offer limited balance billing protections, while only six provide comprehensive balance billing protections for consumers.[67] In addition, for people who would otherwise have been uninsured and now purchase short-term, limited-duration insurance, the final rule will likely result in a decrease in uncompensated care. The Departments have no evidence that this rule will lead to increased emergency department boarding times for mental health patients in emergency departments.

A few commenters stated that short-term, limited-duration insurance coverage also poses a threat to the student health insurance market. Students may buy the cheaper, short-term, limited-duration insurance erroneously thinking that it is comprehensive coverage. Commenters believe that losses to this insurance pool would result in increased premiums for student health coverage for those students that choose or need to stay on their campus student health insurance plan and this could also place considerable stress on the institutions' student health and wellness departments.

The Departments believe that all consumers, including but not limited to students, should have access to additional, more affordable coverage options. In fact, these policies may significantly benefit students since premiums for the young have risen most dramatically as a result of PPACA. However, since most educational institutions require students to obtain insurance through individual market plans or group coverage and often provide relatively inexpensive options to students, the Departments believe that losses to this insurance pool will be limited. As previously stated, the Departments believe that the notice, provided at the time of application and in the contract with the language specified in this final rule, will help consumers understand what they are purchasing. Consumers may also be able to obtain additional guidance and assistance from brokers and agents as well as additional plan documents in order to understand the products they seek to purchase. The Departments generally defer to the states' authority over agents and brokers licensed in their respective jurisdictions, including taking appropriate action in response to unfair or deceptive practices, which should act as a disincentive to such practices.

Some commenters stated that the proposed changes would be harmful for solo entrepreneurs and small business employees by raising rates for individuals dependent on the individual market Exchanges, which is where many small business employees and solo entrepreneurs purchase health coverage. These commenters asserted that in order for employees of small businesses to be able to receive affordable coverage, individual market risk pools must be robust and well balanced.

The Departments acknowledge that the changes finalized in this rule may lead to a small increase in premiums for individual market plans and possibly a reduction in net premiums for Exchange plans. The CMS Office of the Actuary (OACT) estimated that the average net premium paid by Exchange enrollees is expected to decline by 14 percent as a result of the rule.[68] The Departments note, however, that other regulations, such as this rule and the recently finalized rule titled "Definition of "Employer" under Section 3(5) of ERISA—Association Health Plans",[69] issued by the Department of Labor, will increase access to other alternative, less expensive options for small businesses and solo entrepreneurs. Moreover, many small business employees and solo entrepreneurs stand to benefit from this rule. States also maintain flexibility under this final rule to pursue innovative strategies to strengthen and protect their respective risk pools.

Some commenters stated that these changes could result in counties with no Exchange plans available, otherwise known as bare counties. Many commenters stated that these changes would increase the number of uninsured.

The Departments acknowledge that due to the potential increase in risk segmentation, in which healthier individuals choose products outside the individual market may result in an individual market risk pool with higher medical expenses, it is possible that fewer issuers may offer plans in the individual market. However, the impact on issuer participation in the individual market will vary depending on a number of different factors, such as the unique demographic and other characteristics of a state's population, regulatory environment and insurance markets. Further, as a result of silver loading[70] and dramatically higher premiums as well as pricing power from markets with limited competition from other issuers, issuers have begun to turn a profit in the individual market and some issuers are looking to enter the individual market. Further, many enrollees already had access to just one issuer for Exchange coverage. In addition, as discussed below, it is expected that the total number of individuals with some type of health insurance coverage will increase, perhaps significantly.

In response to the request for comments on the value of excluded services to individuals who switch from individual market coverage to short-term, limited-duration coverage, one commenter expressed concern about the suggestion that consumers would be willing to switch from individual market plans that provide more robust coverage to short-term, limited-duration insurance policies that provide less generous coverage because consumers do not believe the more generous benefits are worth the cost. The commenter stated that the Departments

[66] Karen Pollitz, "Surprise Medical Bills", Kaiser Family Foundation, March 17, 2016. Available at *https://www.kff.org/private-insurance/issue-brief/surprise-medical-bills/*.

[67] Kevin Lucia, Jack Hoadley, and Ashley Williams, "Balance Billing by Health Care Providers: Assessing Consumer Protections Across States'", The Commonwealth Fund, June 13, 2017. Available at: *https://www.commonwealthfund.org/publications/issue-briefs/2017/jun/balance-billing-health-care-providers-assessing-consumer* and Berta Alicia Bustamante, "Most States Still Don't Have Comprehensive Balance Billing Legislation", insideARM, October 3, 2017. Available at: *https://www.insidearm.com/news/00043325-most-states-still-dont-have-comprehensive/*.

[68] The net premium reduction is a result of unsubsidized and less-subsidized enrollees exiting the market, leaving the remaining population receiving more premium tax credit, on average. Net premiums for individual enrollees do not fall.

[69] 83 FR 28912.

[70] Silver loading refers to issuers including the entire cost of un-funded cost sharing reduction (CSR) payments on silver metal tier plans which offer CSR plan variants, rather than spread the cost over all metal tier plans.

have not offered any evidence to support such a suggestion and the commenter stated that recent polling indicates the opposite. The commenter referred to a poll [71] where 84 percent of respondents in the individual market stated that they would prefer to stay with their current plan rather than enroll in short-term, limited-duration insurance coverage, when asked if they would like to enroll in coverage that was less generous but with a lower premium. The commenter was also concerned that consumers, when faced with cost concerns, new plan choices, non-transparent plan information, and a confusing enrollment process will not be able to tell whether they are enrolling in a comprehensive plan or not—and consequently will end up with far less coverage than they thought they had.

Many commenters stated that the negative consequences of short-term, limited-duration insurance are not limited to individuals with preexisting conditions; even healthy individuals may be harmed by choosing cheaper, skimpier coverage. If individuals are unable to receive or pay for care solely on the basis of having a less comprehensive health plan, they may put off needed care, and may lose the ability to have cost-effective choice over their health care decisions. Many commenters also stated that enrollees in short-term, limited-duration insurance will face financial hardship if they have an accident or become sick and find out that these policies do not cover benefits such as prescription drugs or some surgeries and that the policies can deny claims that should have been covered or that the enrollees were lead to believe were covered.

One commenter stated that individuals who want the services that are excluded in short-term, limited-duration insurance have the choice to buy individual market plans. If they cannot afford those policies, however, the commenter stated that they would not be able to get the excluded services in the first instance.

One commenter suggested that the proposed changes fail to address (and will likely exacerbate) the most critical needs in the health care and health insurance markets to put downward pressure on the rapidly rising costs of health care in the U.S. and to spread risk across larger, more diverse populations. One commenter stated that the proposals would worsen the inequality between the low and moderate income populations in the individual insurance market.

This rule makes no changes to the federal individual market requirements. The Departments acknowledge that individuals will be able to continue to purchase and renew individual market plans, instead of switching to short-term, limited-duration insurance. Of note, the turbulence of the first several years of the Exchanges with persistent issuer exit resulted in many individuals being unable to renew their individual market plans. Under this final rule, individuals who prefer less expensive coverage, or those that do not qualify for PTCs or otherwise find individual market coverage unattractive, will generally have greater flexibility to purchase short-term, limited-duration insurance and obtain coverage for services they want and exclude services they determine they do not need. The Departments believe that individuals reveal their preferences with their actions and consumers who switch to short-term, limited-duration insurance from individual market plans will do so because they do not value the individual market coverage at the cost. In addition, allowing people to purchase what they view as an efficient amount of coverage leads to less third-party payments, and third-party payments can drive up health care spending as consumers and producers are insensitive to price when third-party payers are paying the bill. Consumers can use their savings from lower premiums toward buying health care services when they are active, informed consumers, looking for the best possible deals.

Because short-term, limited-duration insurance policies can, subject to state law, be priced in an actuarially fair manner (by which the Departments mean that is the policies are priced so that the premium paid by an individual reflects the risks associated with insuring the particular individual or individuals covered by that policy) individuals who purchase such coverage are likely to be relatively young or relatively healthy. Allowing such individuals to purchase a policy that does not comply with PPACA, but with an initial contract term of less than 12-months with renewals or extensions up to maximum duration of 36 months, may weaken states' individual market single risk pools. The degree to which individuals purchase separate renewal guarantee products will serve to strengthen individual market pools and could reduce Exchange premiums and spending—as at least one commenter pointed out. If the individual market deteriorates because of people choosing other types of coverage, individual market issuers could experience higher than expected costs of care and suffer financial losses, which might prompt them to leave the individual market. Although choices of plans available in the individual market have already been reduced to plans from a single issuer in roughly half of all counties, this final rule may further reduce choices for individuals remaining in those individual market single risk pools. However, as a result of silver loading and the tightening of special enrollment periods, some issuers, aware of the Association Health Plan rule and the short-term, limited-duration insurance proposals, have indicated they will expand their presence in the individual market next year.

Impact on Individual Market Risk Pool

This final rule allows short-term, limited-duration insurance policies to be renewed or extended such that the maximum duration of a policy, including the initial term specified in the contract and renewals or extensions under the same insurance contract, is no longer than 36 months. Depending on state rating requirements, issuers of such coverage may be able to introduce new plans every year at low rates that only healthy individuals would be able to purchase, while imposing large renewal rate increases for less healthy enrollees in existing plans. This could lead to further worsening of the risk pool by keeping healthy individuals out of the individual market for longer periods of time, increasing premiums for individual market plans and may cause an increase in the number of individuals who are uninsured. Previous academic research on the pre-PPACA individual market suggests this is unlikely to happen, however, as premium increases generally reflect the entire pool's experience with less healthy individuals effectively subsidized by healthier individuals through market forces.[72] This impact may be further mitigated by the degree that individuals purchase separate renewal guarantee products which may provide another mechanism for consumers to continue coverage under separate short-term, limited-duration

[71] Kaiser Family Foundation. Poll: "Survey of the Non-Group Market Finds Most Say the Individual Mandate Was Not a Major Reason They Got Coverage in 2018, And Most Plan to Continue Buying Insurance Despite Recent Repeal of the Mandate Penalty", April 3, 2018. Available at *https://www.kff.org/health-reform/press-release/poll-most-non-group-enrollees-plan-to-buy-insurance-despite-repeal-of-individual-mandate-penalty/*.

[72] Michael F. Cannon, "Short-Term Plans Would Increase Coverage, Protect Conscience Rights & Improve ObamaCare Risk Pools", Cato Institute, July 2, 2018. Available at *https://www.cato.org/blog/short-term-plans-reducing-uninsured-protecting-conscience-rights-improving-obamacares-risk*.

insurance policies for a longer period of time.[73]

Further, as detailed elsewhere in this rule, the Departments are finalizing a notice requirement to inform consumers about the limitations of short-term, limited-duration insurance to help individuals make informed coverage purchasing decisions that best suits their needs—whether that is comprehensive individual market coverage or short-term, limited-duration insurance. This notice will also assist consumers of short-term, limited-duration insurance in further understanding the products being offered and can be used to combat misleading marketing and aggressive sales tactics that some brokers, agents, or issuers may employ as a result of potentially higher profits and commissions for short-term, limited-duration insurance.

In response to the request for comments on any impacts on PPACA individual market single risk pools, some commenters who supported the proposed rule expressed confidence that the rule would not adversely impact the single risk pools. One commenter stated that the short-term, limited-duration insurance market has been in existence for over three decades and was not accused in the pre-PPACA market of being a destabilizing influence. According to the commenter, the market's modest size, which they estimated to be between 650,000 and 850,000 enrollees before the October 2016 final rule became effective, represents a niche within the broader private health insurance market.

Many commenters, however, expressed concern that extending the maximum duration of short-term, limited-duration coverage would weaken the single risk pools and destabilize the individual market by syphoning young, healthy individuals to the short-term, limited-duration insurance market, leaving only those with higher expected health costs and those receiving subsidies in the individual market. Commenters suggested that the resulting market segmentation and adverse selection would increase premiums for individual market plans and may decrease the number of plans available as issuers exit the individual market, potentially leading to "bare counties". Commenters also suggested that this would transform individual markets into high risk pools and would create a parallel insurance market, undercutting the comprehensive, major medical policies offered to individuals and families.

Many commenters stated that the combination of increased availability of short-term, limited-duration insurance and the reduction of the individual shared responsibility payment to $0, in conjunction with the proposed Association Health Plan rule,[74] could exacerbate adverse selection in the individual market. One commenter stated that premium and cost-sharing subsidies are available only for individual market plans sold on Exchanges, providing incentives for healthy lower-income individuals to remain in such plans and therefore limiting the deterioration of the individual market risk pool. Individuals eligible for premium subsidies would generally be shielded from the premium increases as federal premium subsidies would increase. For unsubsidized individuals who are healthy, higher premiums for individual market plans would increase the attractiveness of lower-premium short-term, limited-duration insurance.

A few commenters stated that these effects on the individual market risk pool could be limited in states that implement additional regulations limiting the length and availability of short-term, limited-duration policies or requiring that they meet rules governing individual market plans.

One commenter stated that if short-term, limited-duration issuers are allowed to increase premiums at renewal based on an individual's health conditions, individuals with new conditions will receive higher rate increases than enrollees without new conditions. The commenter further stated that if there are no limits on the allowable rate increases, premiums for some individuals could exceed those in the individual market. In such a case, the enrollee may move back to the individual market risk pool, increasing the health care costs of the pool.

Many commenters stated that a key element of any healthy, sustainable insurance market is that a broad pool of enrollees share in the spreading of risk. The effect of the proposed rule would be to undercut the individual market risk pool as more individuals leave their current health plans and purchase short-term, limited-duration insurance. This would further destabilize an already difficult market for individual and family coverage.

One commenter suggested the proposed rule assumed that consumers who purchase short-term, limited-duration insurance and then find the insurance inadequate for a health problem that occurs during the term of this insurance will switch to more adequate coverage in the individual market. The commenter noted that the proposed rule fundamentally conceded that it will adversely affect the individual market that is a last resort for those with serious health issues at the same time "the agencies tout the fail safe function of those markets".

Some commenters gave examples where state policies allowing segmentation of the risk pool has led to higher premiums and problems with issuer participation. These commenters mentioned continuation of transitional plans in Iowa, Nebraska, North Carolina and large enrollment numbers in the Tennessee Farm Bureau as examples. A commenter noted that in 2016, the average plan liability risk scores for PPACA-compliant individual market plans in states that allowed the sale of transitional plans were 12.3 percent higher than risk scores for PPACA-compliant individual market plans in states that prohibited transitional policies.

The Departments acknowledge that relatively young, relatively healthy individuals in the middle-class and upper middle-class whose income disqualifies them from obtaining PTCs are more likely to purchase short-term, limited-duration insurance. As people choose these plans rather than individual market coverage, this could lead to adverse selection and the worsening of the individual market risk pool. As discussed below, the Departments estimate that the proportion of healthier individuals in the individual market Exchanges will decrease and by 2028 premiums for unsubsidized enrollees in the Exchanges will increase by 5 percent. The Congressional Budget Office (CBO) projects only a 2 percent to 3 percent impact on premiums in the small group and individual markets from the combined Association Health Plan and short-term, limited-duration insurance rules, even while projecting more people will exit the individual market for these alternatives.[75] Compared to CBO, the OACT analysis thereby represents a more conservative analysis. However, premium and cost-sharing subsidies are available only for individual market plans offered on Exchanges, which makes it likely that healthy lower-income individuals will

[73] Id.

[74] The proposed rule, published in the **Federal Register** on January 5, 2018 (83 FR 614) was subsequently finalized and published in the **Federal Register** on July 12, 2018 (83 FR 28912).

[75] Congressional Budget Office, "Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018 to 2028," May 23, 2018. Available at *http://cbo.gov/publication/53826*.

remain in individual market plans even if they place a relatively low value on this coverage because the individual subsidized premium is so low, limiting the extent of adverse selection. To the extent that individuals purchase separate renewal guarantee products, and continue to use short-term, limited-duration insurance, they very well may not return to the individual market risk pool if they get sick. This will limit the adverse effect on the individual market risk pool. In addition, as discussed below, the total number of individuals with coverage (including short-term, limited-duration insurance) is expected to increase. The impact on individual states' single risk pools will vary depending on state regulations, the current state of the individual market, and the unique demographic and other characteristics of a state's population and insurance markets.

The Departments anticipate that most of the individuals who switch from individual market plans to short-term, limited-duration insurance will be relatively young or relatively healthy and have an annual income—about $48,000 for a single household and $98,000 for a family-of-four—that makes them ineligible to receive PTCs. If the individual market single risk pools change, the change will result in an increase in gross premiums for the individuals remaining in those risk pools. An increase in premiums for individual market single risk pool coverage is expected to result in an increase in federal outlays for PTCs. However, individuals who receive PTCs will be largely insulated from these increases in premiums because a consumer's PTC amount generally increases as the price of the relevant benchmark plan increases. As discussed above, OACT's analysis projects that net premiums in PPACA-compliant markets will decline.[76]

Impact Estimates

The economic impact analysis in the proposed rule provided that because short-term, limited-duration insurance can, subject to state law, be priced in an actuarially fair manner (by which the Departments meant that it is priced so that the premium paid by an individual reflects the risks associated with insuring the particular individual or individuals covered by that policy) individuals who are likely to purchase short-term, limited-duration insurance are likely to obtain a better value than they receive from individual health insurance coverage. The economic impact analysis of the proposed rule also provided that allowing individuals greater choice of policies that do not comply with all of the PPACA market requirements would impact the individual market single risk pools. The Departments[77] estimated that in 2019, between 100,000 and 200,000 individuals previously enrolled in individual market coverage would purchase short-term, limited-duration insurance policies instead. The Departments estimated that this would cause the average monthly individual market premiums and average monthly PTCs to increase, leading to an increase in total annual advance payments of the PTC[78] in the range of $96 million to $168 million in 2019. Other entities project greater enrollment and have different views on whether or not this increases the deficit. The Departments also noted that enrollment in short-term, limited-duration insurance and the resulting reductions in individual market enrollment and increases in individual market premiums in future years are uncertain.

OACT performed an analysis of the financial effects of the proposed rule on April 6, 2018.[79] An updated estimate has been performed by OACT where the baseline was updated to the President's Fiscal Year 2019 Mid-Session Review. As stated in the April 6th estimate, the assumptions and methods used in the updated estimate are the same as those used in OACT's previous health reform modelling.[80] The updated estimate includes the policy to allow renewability up to 36 months. This policy was estimated to have a negligible impact. In addition, consideration was given to some states taking action to prohibit or limit the sale of short-term, limited-duration insurance policies. The original estimate also assumed a 4-year transition to short-term, limited-duration insurance policies with roughly two-thirds of the impact occurring in 2019, while the new estimate assumes a 3-year transition with one-third of the impact occurring in 2019.

Using these updated assumptions yields an estimate that 2019 enrollment in short-term, limited-duration insurance will increase by 600,000. Exchange enrollment in 2019 is expected to decrease by 200,000, while enrollment in off-Exchange plans is expected to decrease by 300,000. The remaining 100,000 increase in short-term, limited-duration enrollment is largely accounted for by new consumers who were previously uninsured. By 2028, enrollment in individual market plans is projected to decrease by 1.3 million, while enrollment in short-term, limited-duration insurance will increase by 1.4 million. The net result will be an increase in the total number of people with some type of coverage by 0.1 million in 2020 and by 0.2 million by 2028. Premiums for unsubsidized enrollees in the Exchanges are expected to increase by 1 percent in 2019 and by 5 percent in 2028. Individuals who choose to purchase short-term, limited-duration insurance are expected to pay a premium that is approximately half of the average unsubsidized premium in the Exchange. Since individual market plan premiums are expected to increase the study estimates that PTCs will increase by $0.2 billion in 2019 and by a net total of $28.2 billion for fiscal years 2019–2028.

TABLE 2—ESTIMATED EFFECT OF SHORT-TERM, LIMITED-DURATION INSURANCE POLICY CHANGES 2019–2028

Calendar year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–28
Enrollment Impact:											
Exchange	−0.2	−0.4	−0.6	−0.6	−0.6	−0.6	−0.6	−0.6	−0.6	−0.6	.....
Off-Exchange [1]	−0.3	−0.7	−0.8	−0.8	−0.8	−0.8	−0.7	−0.7	−0.7	−0.7	.....

[76] The net premium reduction is a result of unsubsidized and less-subsidized enrollees exiting the market, leaving the remaining population receiving more premium tax credit, on average. Net premiums for individual enrollees do not fall.

[77] For purposes of the economic impact analysis in the proposed rule, the term "the Departments" was used to refer to HHS and the Department of Labor.

[78] The Departments used data on Advance PTC as an approximation of PTC since this is the data that is available for 2017.

[79] CMS Office of the Actuary, "Estimated Financial Effects of the Short-Term, Limited-Duration Policy Proposed Rule," April 6, 2018. Available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/STLD20180406.pdf.*

[80] CMS Office of the Actuary, "Estimated Financial Effect of the "American Health Care Act of 2017"" June 13, 2017. Available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/AHCA20170613.pdf.*

TABLE 2—ESTIMATED EFFECT OF SHORT-TERM, LIMITED-DURATION INSURANCE POLICY CHANGES 2019–2028—Continued

Calendar year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–28
Short-term, limited-duration	0.6	1.3	1.6	1.6	1.5	1.5	1.5	1.5	1.5	1.4	.....
Total	0.0	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	
Premium Impact:											
Marketplace.											
Gross Premium	1%	3%	5%	5%	5%	5%	5%	5%	5%	5%	.....
Net Premium[2]	−6%	−11%	−14%	−14%	−14%	−14%	−14%	−14%	−14%	−14%	.....
Short-term, limited-duration.											
Gross Premium[3]	−41%	−45%	−49%	−49%	−49%	−49%	−49%	−49%	−49%	−49%	.....
Fiscal year	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–28
Federal Impact [$ Billions]:											
Premium Tax Credits	$0.2	$1.2	$2.5	$3.0	$3.1	$3.3	$3.4	$3.6	$3.8	$4.0	$28.2

[1] Off-Exchange coverage includes enrollment in plans that we assume would meet the definition of insurance coverage. Most of these individuals are assumed to be enrolled in individual market plans.
[2] Net premium is the actual premium paid by the consumer after accounting for any subsidies such as premium tax credits. The net premium reduction is a result of unsubsidized and less-subsidized enrollees exiting the market, leaving the remaining population receiving more premium tax credit, on average. Net premiums for individual enrollees do not fall.
[3] The change in gross premium for those choosing a short-term, limited-duration policy is measured relative to the average gross premium in the Exchange.
Note: Impact on Exchange enrollment in 2018 is expected to be minimal.

There is significant uncertainty regarding these estimates, because changes in enrollment and premiums will depend on a variety of economic and regulatory factors and it is difficult to predict how consumers and issuers will react to the changes finalized in this rule. In addition, the impact in any given state will vary depending on state regulations and the characteristics of that state's markets and risk pools.

OACT was not the only entity to model the impacts of the proposed regulation. CBO, along with the Joint Committee on Taxation (CBO and JCT), the Urban Institute, and the Commonwealth Fund also looked at the impact. CBO and JCT estimated the impacts of the proposed regulation in their May 2018 report on "Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018 to 2028".[81] CBO and JCT found that 2 million people would be covered by short-term, limited-duration insurance in 2023, and that "65 percent of the 2 million purchasing [short-term, limited-duration] plans would have been insured in the absence of the proposed rules". This estimate projected higher uptake of short-term, limited-duration insurance among those that were not previously insured than OACT estimated.[82] Additionally, CBO projected higher overall enrollment in short-term, limited-duration coverage, 2 million people in 2023 compared to OACTs estimate of 1.5 million in 2023. Notably, CBO assumed an increase in short-term, limited-duration insurance policy duration to less than 12 months, but did not analyze the impacts of allowing extensions up to 36 months, which would have presumably increased their take-up rates even further. Also, notable is that when estimating the combined effects of this regulation and the recently finalized Association Health Plan rule, CBO found that "premiums are projected to be 2 percent to 3 percent higher in those markets [small group and individual market] in most years." Despite higher take-up rates, CBO and JCT expect lower premium increases for coverage that complies with all of the PPACA market requirements than OACT. CBO and JCT also found that in combination, "the proposed rules [short term limited duration insurance and association health plans] would reduce the federal deficit by roughly $1 billion over the 2019–2028 period if implemented as proposed." They stated that, "over the 2019–2028 period, outlays for marketplace subsidies would increase on net by $2 billion, and revenues would increase by $3 billion. The net increase in marketplace subsidies reflects an increase in subsidies stemming from higher premiums, mostly offset by a reduction in the number of people receiving those subsidies." CBO and JCT further stated that "On the basis of information obtained from stakeholders, CBO and JCT project that the rule on AHPs would primarily affect the small-group market and that the rule on STLDI plans would primarily affect the non-group market." Relative to OACT's estimates, CBO and JCT estimated the impacts of this rule to result in more short-term, limited-duration plan take-up with a larger share of the take-up coming from people who were not previously insured, lower premium impacts for PPACA-compliant coverage, and a lower cost to the federal government.[83]

CBO and JCT were not the only entities to analyze the quantitative impacts of the proposed rule. The Urban Institute ran a state-level microsimulation model (taking into account market conditions in each state as well as regulatory differences) and also estimated that an extension of short-term, limited-duration insurance to less than 12 months would result in greater take-up of the plans than OACT estimated, as well as savings for the federal government.[84] Specifically the Urban Institute found that in 2019 "4.3 million would enroll in expanded short-term limited-duration plans."[85] "About 1.7 million of the people buying [short-term, limited-duration insurance] policies would have been uninsured (in the traditional sense) under current law, and 2.6 million [short-term, limited-

[81] Congressional Budget Office, "Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018 to 2028," May 23, 2018. Available at *http://cbo.gov/publication/53826.*

[82] CBO noted that, "of the 2 million additional enrollees in STLDI plans, fewer than 500,000 would purchase products not providing comprehensive financial protection against high-cost, low-probability medical events. CBO considers such people uninsured."

[83] CBO and JCT did not separately break out the budget effects of the AHP rule and the short-term, limited-duration rule.

[84] L.J. Blumberg, M. Buettgens, R. Wang, "The Potential Impact of Short-Term Limited-Duration Policies on Insurance Coverage, Premiums, and Federal Spending," Urban Institute, March 2018. Available at: *https://www.urban.org/sites/default/files/publication/96781/2001727_updated_finalized.pdf.*

[85] Id.

duration] policy holders would otherwise have had insurance of some type." They further found that "ACA-compliant non-group coverage would decrease by another 2.2 million people. About 70 percent of that decrease (1.6 million people) comes from fewer people buying PPACA-compliant coverage without a tax credit, and about 30 percent of the decrease (about 600,000 people) comes from fewer people buying non-group insurance with a tax credit." As a result of their estimate of the decrease in the number of people receiving tax credits they estimated the policy to result in net savings to the federal government of $721 million in 2019. The Urban Institute grouped the individual mandate penalty being reduced to $0 and the short-term, limited-duration proposal to estimate the premium effects on individual market single risk pools, so it is difficult to know what just the policy impact of short term changes would have been to premiums in their analysis. In sum, relative to OACT's analysis, Urban estimates savings to the federal government (rather than costs), as well as materially higher take-up (4.3 million in 2019 versus 1.4 million in 2028), including among those that previously did not have insurance (1.7 million in 2019 versus 0.2 million in 2028).

While CBO and the Urban Institute appear to have done robust work on the issue, other entities also provided estimates of the impact. The Commonwealth Fund concluded that if there are no behavioral barriers to enrollment in short-term, limited-duration plans, and under a baseline of no individual shared responsibility payment, extending the duration of short-term, limited-duration insurance would result in about 5.2 million people enrolled.[86] The Commonwealth Fund estimated that the average premium for a short-term, limited-duration insurance policy will be roughly 80 percent cheaper than silver plans and about 70 percent cheaper than bronze plans for a 40-year old.[87] The Commonwealth Fund estimated that "the age-specific premium for a silver plan increases by 0.9 percent (from $7,308 to $7,377) relative to current law when the individual mandate is lifted, and by 3.6 percent (from $7,308 to $7,568) when the mandate is lifted and behavioral barriers are removed" (implying the marginal effect of adding short term plans in a scenario with limited behavior barriers was roughly 2.7 percent). The Commonwealth Fund did not provide estimates of cost impacts to the federal government.

In response to the Departments' request for comments on how many consumers may choose to purchase short-term, limited-duration insurance, rather than being uninsured or purchasing individual market plans, many commenters submitted or referred to studies that estimated the impact of the proposed changes. Some of these studies and findings have been described above. Another study conducted by the Wakely Consulting Group[88] estimated that, as a result of the proposed changes and the reduction of the individual shared responsibility payment to $0, premiums would increase by 0.7 percent to 1.7 percent and enrollment would decrease by 2.7 percent to 6.4 percent in the individual market in 2019. In addition, the study estimated that premiums for individual market plans would increase 2.2 percent to 6.6 percent and enrollment would decrease by 8.2 percent to 15 percent in 4 to 5 years, when the full impact of the proposed changes can be felt. A study by Oliver Wyman,[89] focusing on the District of Columbia's individual and small group markets, estimated that the combined effect of the proposed changes and the reduction of the individual shared responsibility payment to $0 would be an increase in claims costs by 11.7 percent to 21.4 percent and a decrease in enrollment in individual and small group plans of 3,800 to 6,100 in Washington, DC. Notably Washington DC's individual market is highly idiosyncratic in terms of the number of people in it not receiving subsidies, so the effects on that market are unlikely to be comparable with other states. A study by Covered California[90] concluded that the combined effect of the proposed Association Health Plan rule and the short-term, limited-duration rule would increase premiums by 0.3 percent to 1.3 percent in the individual market in California in 2019.

Many commenters stated that the proposed rule likely underestimates the number of people who would enroll in short-term, limited-duration insurance and thus underestimates the premium and risk pool impact of the proposed changes. Commenters suggested that it is insufficient to look at prior data on short-term, limited-duration insurance enrollment to predict what would happen as a result of the proposed change in federal rules, since conditions for the short-term, limited-duration insurance market are poised to differ markedly from recent years. Commenters noted that in 2019, the individual shared responsibility payment will be reduced to $0, removing one factor that has likely kept more people from enrolling in short-term, limited-duration insurance. Commenters also noted that the federal government is actively promoting short-term, limited-duration insurance and pulling back on its outreach efforts for individual market plans, a reversal of prior policy that is likely to increase short-term, limited-duration insurance enrollment, and that major issuers have already expressed interest in offering or expanding offerings of short-term, limited-duration plans.

One commenter stated that the total enrollment in short-term, limited-duration insurance was actually close to 500,000 covered lives in December 2016 after accounting for association-based sales. The commenter further noted that as a result of the reduction of the individual shared responsibility payment to $0 beginning in 2019, the cost differential between short-term,

[86] Preethi Rao, Sarah A. Nowak, Christine Eibner, "What Is the Impact on Enrollment and Premiums if the Duration of Short-Term Health Insurance Plans Is Increased?", Commonwealth Fund, June 5 2018. Available at *https://www.commonwealthfund.org/publications/fund-reports/2018/jun/what-impact-enrollment-and-premiums-if-duration-short-term*. Examples the Commonwealth Fund cited of behavioral barriers to enrollment include "increased marketing of plans to increase awareness, streamlining the application process, lack of concern over facing the mandate penalty."

[87] Preethi Rao, Sarah A. Nowak, Christine Eibner, "What Is the Impact on Enrollment and Premiums if the Duration of Short-Term Health Insurance Plans Is Increased?", Commonwealth Fund, June 5 2018. Available at *https://www.commonwealthfund.org/publications/fund-reports/2018/jun/what-impact-enrollment-and-premiums-if-duration-short-term*. In a scenario with behavioral barriers in place, they estimated a materially lower number of 0.3 million in take-up. Examples the Commonwealth Fund cited of behavioral barriers to enrollment include "increased marketing of plans to increase awareness, streamlining the application process, lack of concern over facing the mandate penalty." Market forces may well come up with ways of addressing these behavioral barriers—such as by marketing the plans aggressively, providing a high quality customer experience in a streamlined application process, and clarifying the applicability of the mandate penalty.

[88] Michael Cohen, Michelle Anderson, Ross Winkelman, "Effects of Short-Term Limited Duration Plans on the ACA-Compliant Individual Market," Wakely Consulting Group, April, 2018. Available at: *http://www.communityplans.net/wp-content/uploads/2018/04/Wakely-Short-Term-Limited-Duration-Plans-Report.pdf*.

[89] Oliver Wyman, "Potential Impact of Short-Term Limited Duration Plans," April 11, 2018. Available at: *https://hbx.dc.gov/sites/default/files/dc/sites/hbx/publication/attachments/OWReview%20of%20Impact%20of%20Short%20Term%20Duration%20Plans%204.11.2018%28002%29.pdf*.

[90] Covered California, "Individual Markets Nationally Face High Premium Increases in Coming Years Absent Federal or State Action, With Wide Variation Among States," March 8, 2018. Available at *http://hbex.coveredco.com/data-research/library/CoveredCA_High_Premium_Increases_3-8-18.pdf*.

limited-duration insurance and individual market plans will increase, and enrollment in short-term, limited-duration insurance is likely to grow beyond what it was in 2016. The commenter estimated that each percentage point increase in premiums for individual market plans as a result of the policies in the proposed rule would increase federal spending on PTCs by $800 million in 2019. Another commenter cited a report stating that enrollment in short-term, limited-duration coverage may be closer to one million.

One commenter expected that the mostly uninsured or off-Exchange insured group of consumers who may purchase short-term, limited-duration insurance policies will follow the age distribution of those who currently purchase short-term, limited-duration insurance, which is an average of approximately 41.3 years of age.

The Departments are unable to verify the conclusions of the different studies submitted and referred to by commenters. However, the studies, in sum suggest that the rule may significantly reduce the number of people without any type of health insurance and will likely only result in a small average increase to premiums in the individual and group markets.

Enrollment in short-term, limited-duration insurance will depend in large part on how issuers respond to this final rule and to external factors such as the reduction to $0 of the individual shared responsibility payment starting in 2019. If issuers respond by offering a substantially greater range of plan designs than those currently available in the market for short-term, limited-duration insurance in order to attract consumers with a wide range of medical needs, then total enrollment is more likely to align with high-end estimates. Alternatively, if states impose restrictions on short-term, limited-duration insurance or issuers do not substantially alter existing short-term, limited-duration insurance plan designs, then consumers may experience only a moderate increase in convenience as a result of this final rule since short-term, limited-duration insurance is already available and can be purchased as four separate less than 3-month insurance policies [91]—and in such a scenario, high-end enrollment estimates would be less likely.

As discussed earlier in this rule, there is significant uncertainly regarding all of these estimates, because changes in enrollment and premiums will depend on a variety of factors and it is difficult to predict how consumers and issuers will react to the policy changes finalized in this rule. In addition, the impact in any given state will vary depending on state regulations and the characteristics of that state's markets and risk pools. In addition, some of these studies estimate the impacts of the proposed rule and some of them present combined effects of the Association Health Plan proposed rule or the reduction of the shared responsibility payment to $0. The study by Oliver Wyman may not be generally applicable to the rest of the country, because the District of Columbia is not representative of other markets insofar as it is very small and because a very small percentage of the District's enrollees receive PTCs.

C. Regulatory Alternatives

The Departments considered not changing the federal standards for short-term, limited-duration insurance or increasing the initial contact term to 6 or 8 months, as suggested by some commenters. However, this alternative would not adequately increase choices for individuals unable or unwilling to purchase individual market health insurance coverage. Extending the maximum initial contract term to less than 12 months ensures that deductibles are not reset and premiums do not increase every 3 (or 6, or 8) months for consumers who purchase short-term, limited-duration insurance and conditions that develop during the coverage period continue to be covered for a longer period of time until the consumer can switch to an individual market plan, if needed

The Departments considered finalizing the notice language as proposed. The Departments decided to revise the notice language based on commenter feedback to include more details regarding what the policy may or may not cover. States also have the option to require more information than what is included in the federal notice.

The Departments considered not allowing renewals or extensions of short-term, limited-duration insurance policies beyond 12 months, as well as not permitting renewals or extensions. However, upon review of comments, the Departments determined that allowing renewals or extensions of a policy up to a maximum duration of 36 months increases consumer choices, provides additional protection, and ensures that consumers can maintain coverage under their short-term, limited-duration insurance policy after the expiration of the initial contract term if it is the most desirable option. As many commenters pointed out, to the extent that the maximum duration of short-term, limited-duration insurance is limited to a relatively short period of time, for example, less than 3 months, or even less than 12 months, without permitting renewals or extensions, this would mean that every 3 months or every 12 months, an individual purchasing short-term, limited-duration insurance would be subject to re-underwriting, and would possibly have his or her premium greatly increased as a result. Also, to the extent the policy excluded preexisting conditions for a specified period of time or imposed a waiting period on specific benefits, the individual would not get credit for the amount of time he or she had the previous coverage. The issuer could also decline to issue a new policy to the consumer based on preexisting medical conditions. The Departments find all of these to be compelling reasons in favor of permitting renewals and extensions as set forth in the final rule, such that the maximum duration under a single short-term, limited-duration insurance policy may be 36 months (including renewal or other extension periods), as opposed to less than 12 months. As mentioned earlier in the preamble, in determining the appropriate limits on the permissible range of renewals or extensions in giving meaning to the term "limited-duration," the Departments were informed by other circumstances under which Congress authorized temporary limited coverage options.

In addition to the applicability date set forth in the proposed rule, the Departments also considered an applicability date of January 1, 2020, as suggested by some commenters. The Departments chose the applicability date of 60 days after the date the rule was published in the **Federal Register** to ensure that states that want to expand access to short-term, limited-duration insurance and individuals who wish to purchase such coverage can begin to benefit from the changes as soon as possible.

Some commenters criticized the Departments for not adequately, or failing to, consider other alternatives. Some commenters stated that the Departments failed to explore the options presented in the regulatory alternatives section and should engage in a more robust discussion of regulatory alternatives. One commenter stated that the Departments indicated that the only alternatives to this

[91] Karen Pollitz, Michelle Long, Ashley Semanskee, and Rabah Kamal, "Understanding Short-Term Limited Duration Health Insurance", Kaiser Family Foundation, April 23, 2018. Available at *https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/.*

proposal would be to lengthen the duration of short-term, limited-duration plans to either 6 or 9 months and dismissed both options without any explanation. This suggested, the commenter stated, that the Departments did not adequately consider other options. The commenter suggested that there are other options that will actually lead to expanded access and will not destabilize the private health insurance market, such as to fund cost-sharing reductions. Another option suggested by a commenter was to take no action since, in the commenter's view, the proposed action would not expand access to comprehensive coverage, would lead to more discrimination against people with preexisting conditions, and would destabilize private health insurance markets.

The Departments disagree. In addition to considering maintaining the less than 3 month (including renewals) standard in the October 2016 final rule, as well as the proposed less than 12 month standard in the proposed rule, the Departments also considered maximum durations of 6 months or 8 months. Recognizing the myriad number of potential approaches the Departments could consider to establish federal standards for short-term, limited-duration insurance, the Departments also solicited comments on all aspects of the proposed rule. In addition, we have added a more detailed discussion of regulatory alternatives considered for this final regulation. The Departments have chosen the alternatives that we believe will benefit individuals who have been harmed by the increasing premiums, deductibles and cost-sharing associated with individual market plans and limited choices. As discussed previously, this rule will also increase the number of people with some type of coverage by 0.2 million by 2028.

D. Paperwork Reduction Act—Department of Health and Human Services

This final rule revises the required notice that must be prominently displayed in the contract and in any application materials for short-term, limited-duration insurance. The Departments are providing the exact text for this notice requirement and the language will not need to be customized. The burden associated with these notices is not subject to the Paperwork Reduction Act of 1995 in accordance with 5 CFR 1320.3(c)(2) because they do not contain a "collection of information" as defined in 44 U.S.C. 3502(3). Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 604 of the RFA requires that the agency prepare a final regulatory flexibility analysis describing the impact of the rule on small entities. Small entities include small businesses, organizations and governmental jurisdictions.

The RFA generally defines a "small entity" as—(1) a proprietary firm meeting the size standards of the Small Business Administration (13 CFR 121.201); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of "small entity"). The Departments use as their measure of significant economic impact on a substantial number of small entities a change in costs or revenues of more than 3 to 5 percent.

This final rule will impact health insurance issuers, especially those in the individual market. The Departments believe that health insurance issuers will be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less are considered small entities for this North American Industry Classification System codes. Some issuers could possibly be classified in 621491 (Health Maintenance Organization Medical Centers) and, if this is the case, the SBA size standard is $32.5 million or less.[92] The Departments believe that few, if any, insurance companies selling comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2016 MLR reporting year,[93] approximately 85 out of over 520 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less, of which 51 issuers offer plans in the individual market. This estimate may overstate the actual number of small health insurance companies that may be affected, since almost 79 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $38.5 million. Therefore, the Departments certify that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires agencies to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This final rule will not have a direct effect on rural hospitals, though there might be an indirect impact. However, as discussed below, there are mitigating factors. Therefore, the Departments have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

One commenter disagreed with the statement in the proposed rule that "[t]his proposed rule will not affect small rural hospitals." The commenter stated that issuer withdrawal from the individual market caused by the proposed changes would especially have a catastrophic impact on rural families who already have limited plan choices, as well as on the rural hospitals and other providers who "rely on razor-thin financial margins to deliver care." The commenter urged the Departments to prioritize market stabilization and to pay special attention to the impacts in rural communities.

The total number of individuals purchasing either individual market plans or short-term, limited-duration insurance coverage is expected to increase, which will limit or reduce the amount of uncompensated care provided by hospitals. Moreover, people in rural areas have generally been most harmed by the reduction in choice that as resulted from PPACA and likely stand to disproportionately receive benefit from this rule. The Departments

[92] U.S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes", Effective October 1, 2017. Available at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf.*

[93] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

acknowledge there is a possibility that due to adverse selection and changes to the individual market risk pool, fewer issuers may offer individual market plans in certain states, leading to reduced choices for consumers remaining in the individual market risk pools. However, individuals in rural areas are more likely to be low-income and less likely to receive employer sponsored coverage compared to those living in other areas and a large percentage of rural individuals (24 percent of the nonelderly population) are covered by Medicaid.[94] Individuals in rural areas enrolled in individual market plans are more likely to receive PTC[95] because, generally, incomes in these areas are typically lower than 400% of the Federal Poverty Line and therefore relatively young or healthy individuals are less likely to leave the individual market risk pool in these areas, thereby limiting the effects on the risk pool. State regulations may also limit the impact on the individual market risk pools.

F. Impact of Regulations on Small Business—Department of the Treasury

Pursuant to section 7805(f) of the Code, the proposed rule that preceded this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This final rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have "substantial direct effects" on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the final regulation.

Federal officials have discussed the issues related to short-term, limited-duration insurance with state regulatory officials. This final rule has no federalism implications to the extent that current state law requirements for short-term, limited-duration insurance are the same as or more restrictive than the Federal standard in this final rule. States may continue to apply such state law requirements. States also have the flexibility to require additional consumer disclosures and to establish a different, shorter initial contact term and maximum duration (including renewals and extensions) under state law in response to market-specific needs or concerns.

I. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and to the Comptroller General for review in accordance with such provisions.

J. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This final rule is an Executive Order 13771 deregulatory action.

IV. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1135 and 1191c; and Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, 2792 and 2794 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92 and 300gg–94), as amended.

List of Subjects

26 CFR Part 54

Pension excise taxes.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Parts 144 and 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

Douglas W. O'Donnell,

Acting Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 26, 2018.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 26th day of July 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: July 24, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 25, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons stated in the preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION AND EXCISE TAX

■ **Paragraph 1.** The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *.

■ **Par. 2.** Section 54.9801–2 is amended by revising the definition of "Short-

[94] Julia Foutz, Samantha Artiga, and Rachel Garfield, "The Role of Medicaid in Rural America", Kaiser Family Foundation, April 25, 2017. Available at: *https://www.kff.org/medicaid/issue-brief/the-role-of-medicaid-in-rural-america/.*

[95] Analysis of data on Exchange plan selections (non-canceled plan selections at a point-in-time) for the most recent open enrollment period shows that consumers in rural areas are 5 percent more likely to receive PTC compared to those who live in non-rural areas.

term, limited-duration insurance" to read as follows:

§ 54.9801–2 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 1, excluding the heading "Notice 1," with any additional information required by applicable state law:

Notice 1:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 2, excluding the heading "Notice 2," with any additional information required by applicable state law:

Notice 2:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage.

(4) If a court holds the 36-month maximum duration provision set forth in paragraph (1) of this definition or its applicability to any person or circumstances invalid, the remaining provisions and their applicability to other people or circumstances shall continue in effect.

* * * * *

■ **Par. 3.** Section 54.9833–1 is amended by revising the section heading and the last sentence to read as follows:

§ 54.9833–1 Applicability dates.

* * * Notwithstanding the previous sentence, the definition of "short-term, limited-duration insurance" in § 54.9801–2 applies October 2, 2018.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 4. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 5. Section 2590.701–2 is amended by revising the definition of "Short-term, limited-duration insurance" to read as follows:

§ 2590.701–2 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 1, excluding the heading "Notice 1," with any additional information required by applicable state law:

Notice 1:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 2, excluding the heading "Notice 2," with any additional information required by applicable state law:

Notice 2:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage.

(4) If a court holds the 36-month maximum duration provision set forth in paragraph (1) of this definition or its

applicability to any person or circumstances invalid, the remaining provisions and their applicability to other people or circumstances shall continue in effect.

* * * * *

■ 6. Section 2590.736 is amended by revising the last sentence to read as follows:

§ 2590.736 Applicability dates.

* * * Notwithstanding the previous sentence, the definition of "short-term, limited-duration insurance" in § 2590.701–2 applies October 2, 2018.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 146, and 148 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 7. The authority citation for part 144 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 8. Section 144.103 is amended by revising the definition of "Short-term, limited-duration insurance" to read as follows:

§ 144.103 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 1, excluding the heading "Notice 1," with any additional information required by applicable state law:

Notice 1:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 2, excluding the heading "Notice 2," with any additional information required by applicable state law:

Notice 2:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage.

(4) If a court holds the 36-month maximum duration provision set forth in paragraph (1) of this definition or its applicability to any person or circumstances invalid, the remaining provisions and their applicability to other people or circumstances shall continue in effect.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 9. The authority citation for part 146 is revised to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92.

■ 10. Section 146.125 is amended by revising the last sentence to read as follows.

§ 146.125 Applicability dates.

* * * Notwithstanding the previous sentence, the definition of "short-term, limited-duration insurance" in § 144.103 of this subchapter applies October 2, 2018.

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 11. The authority citation for part 148 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 12. Section 148.102 is amended by revising the section heading and the last sentence of paragraph (b) to read as follows:

§ 148.102 Scope and applicability date.

* * * * *

(b) * * * Notwithstanding the previous sentence, the definition of "short-term, limited-duration insurance" in § 144.103 of this subchapter is applicable October 2, 2018.

[FR Doc. 2018–16568 Filed 8–1–18; 8:45 am]

BILLING CODE 4150–29–P 4830–01–P 4120–01–P 6325–64–P

Grp. Ex. 4
(Part 1 of 2)

IIB

116TH CONGRESS
1ST SESSION

H. R. 987

IN THE SENATE OF THE UNITED STATES

MAY 20, 2019

Received; read twice and referred to the Committee on Health, Education, Labor, and Pensions

AN ACT

To amend the Patient Protection and Affordable Care Act to provide for Federal Exchange outreach and educational activities.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Strengthening Health Care and Lowering Prescription Drug Costs Act".

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—LOWERING PRESCRIPTION DRUG COSTS

Subtitle A—Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics

Sec. 101. Change conditions of first generic exclusivity to spur access and competition.

Subtitle B—Protecting Consumer Access to Generic Drugs

Sec. 111. Unlawful agreements.
Sec. 112. Notice and certification of agreements.
Sec. 113. Forfeiture of 180-day exclusivity period.
Sec. 114. Commission litigation authority.
Sec. 115. Statute of limitations.

Subtitle C—Creating and Restoring Equal Access to Equivalent Samples

Sec. 121. Actions for delays of generic drugs and biosimilar biological products.
Sec. 122. REMS approval process for subsequent filers.
Sec. 123. Rule of construction.

Subtitle D—Study on Role of Federal Assistance in Drug Development

Sec. 131. Study on role of Federal assistance in drug development.

Subtitle E—Pharmacy School Outreach

Sec. 141. Pharmacy school outreach.

Subtitle F—Reports

Sec. 151. Effects of increases in prescription drug price.

TITLE II—HEALTH INSURANCE MARKET STABILIZATION

Sec. 201. Preserving State option to implement health care marketplaces.
Sec. 202. Providing for additional requirements with respect to the navigator program.
Sec. 203. Federal Exchange outreach and educational activities and annual enrollment targets.
Sec. 204. Short-term limited duration insurance rule prohibition.
Sec. 205. Protection of health insurance coverage in certain Exchanges.
Sec. 206. Sense of Congress relating to the practice of silver loading.
Sec. 207. Consumer outreach, education, and assistance.

Sec. 208. GAO report.
Sec. 209. Report on the effects of website maintenance during open enrollment.

TITLE III—BUDGETARY EFFECTS

Sec. 301. Determination of budgetary effects.

TITLE I—LOWERING PRESCRIPTION DRUG COSTS

Subtitle A—Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics

SEC. 101. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking "180 days after" and all that follows through the period at the end and inserting the following: "180 days after the earlier of—

"(aa) the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

"(bb) the applicable date specified in subclause (III).''; and

(2) by adding at the end the following new subclause:

"(III) APPLICABLE DATE.—The applicable date specified in this subclause, with respect to an application for a drug described in subclause (I), is the date on which each of the following conditions is first met:

"(aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

"(bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.

"(cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

"(dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an

application is subsequently approved.".

Subtitle B—Protecting Consumer Access to Generic Drugs

SEC. 111. UNLAWFUL AGREEMENTS.

(a) AGREEMENTS PROHIBITED.—Subject to subsections (b) and (c), it shall be unlawful for an NDA or BLA holder and a subsequent filer (or for two subsequent filers) to enter into, or carry out, an agreement resolving or settling a covered patent infringement claim on a final or interim basis if under such agreement—

(1) a subsequent filer directly or indirectly receives from such holder (or in the case of such an agreement between two subsequent filers, the other subsequent filer) anything of value, including a license; and

(2) the subsequent filer agrees to limit or forego research on, or development, manufacturing, marketing, or sales, for any period of time, of the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (g)(8).

(b) EXCLUSION.—It shall not be unlawful under subsection (a) if a party to an agreement described in such subsection demonstrates by clear and convincing evidence

that the value described in subsection (a)(1) is compensation solely for other goods or services that the subsequent filer has promised to provide.

(c) LIMITATION.—Nothing in this section shall prohibit an agreement resolving or settling a covered patent infringement claim in which the consideration granted by the NDA or BLA holder to the subsequent filer (or from one subsequent filer to another) as part of the resolution or settlement includes only one or more of the following:

(1) The right to market the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (g)(8) in the United States before the expiration of—

(A) any patent that is the basis of the covered patent infringement claim; or

(B) any patent right or other statutory exclusivity that would prevent the marketing of such covered product.

(2) A payment for reasonable litigation expenses not to exceed $7.5 million in the aggregate.

(3) A covenant not to sue on any claim that such covered product infringes a patent.

(d) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) GENERAL APPLICATION.—The requirements of this section apply, according to their terms, to an NDA or BLA holder or subsequent filer that is—

(A) a person, partnership, or corporation over which the Commission has authority pursuant to section 5(a)(2) of the Federal Trade Commission Act (15 U.S.C. 45(a)(2)); or

(B) a person, partnership, or corporation over which the Commission would have authority pursuant to such section but for the fact that such person, partnership, or corporation is not organized to carry on business for its own profit or that of its members.

(2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES ENFORCEMENT AUTHORITY.—

(A) IN GENERAL.—A violation of this section shall be treated as an unfair or deceptive act or practice in violation of section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

(B) POWERS OF COMMISSION.—Except as provided in subparagraph (C) and paragraphs (1)(B) and (3)—

(i) the Commission shall enforce this section in the same manner, by the same

means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

(ii) any NDA or BLA holder or subsequent filer that violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act.

(C) JUDICIAL REVIEW.—In the case of a cease and desist order issued by the Commission under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section, a party to such order may obtain judicial review of such order as provided in such section 5, except that—

(i) such review may only be obtained in—

(I) the United States Court of Appeals for the District of Columbia Circuit;

(II) the United States Court of Appeals for the circuit in which the

ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any successor thereto, of the NDA or BLA holder (if any such holder is a party to such order) is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (g)(8) or an approved application that is deemed to be a license for a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148; 124 Stat. 817) is submitted to the Commissioner of Food and Drugs; or

(III) the United States Court of Appeals for the circuit in which the ultimate parent entity, as so defined, of any subsequent filer that is a party to such order is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection

(g)(8) is submitted to the Commissioner of Food and Drugs; and

(ii) the petition for review shall be filed in the court not later than 30 days after such order is served on the party seeking review.

(3) ADDITIONAL ENFORCEMENT AUTHORITY.—

(A) CIVIL PENALTY.—The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any NDA or BLA holder or subsequent filer that violates this section.

(B) SPECIAL RULE FOR RECOVERY OF PENALTY IF CEASE AND DESIST ORDER ISSUED.—

(i) IN GENERAL.—If the Commission has issued a cease and desist order in a proceeding under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section—

(I) the Commission may commence a civil action under subparagraph (A) to recover a civil penalty against any party to such order at any time before the expiration of the

1-year period beginning on the date on which such order becomes final under section 5(g) of such Act (15 U.S.C. 45(g)); and

(II) in such civil action, the findings of the Commission as to the material facts in such proceeding shall be conclusive, unless—

(aa) the terms of such order expressly provide that the Commission's findings shall not be conclusive; or

(bb) such order became final by reason of section 5(g)(1) of such Act (15 U.S.C. 45(g)(1)), in which case such findings shall be conclusive if supported by evidence.

(ii) RELATIONSHIP TO PENALTY FOR VIOLATION OF AN ORDER.—The penalty provided in clause (i) for violation of this section is separate from and in addition to any penalty that may be incurred for violation of an order of the Commission under

section 5(l) of the Federal Trade Commission Act (15 U.S.C. 45(l)).

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The amount of a civil penalty imposed in a civil action under subparagraph (A) on a party to an agreement described in subsection (a) shall be sufficient to deter violations of this section, but in no event greater than—

(I) if such party is the NDA or BLA holder (or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1)), the greater of—

(aa) three times the value received by such NDA or BLA holder (or by such subsequent filer) that is reasonably attributable to the violation of this section; or

(bb) three times the value given to the subsequent filer (or to the other subsequent filer)

reasonably attributable to the violation of this section; and

(II) if such party is the subsequent filer (or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1)), 3 times the value received by such subsequent filer that is reasonably attributable to the violation of this section.

(ii) FACTORS FOR CONSIDERATION.—In determining such amount, the court shall take into account—

(I) the nature, circumstances, extent, and gravity of the violation;

(II) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA or BLA holder (or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1)),

compensation received by the subsequent filer (or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1)), and the amount of commerce affected; and

(III) other matters that justice requires.

(D) INJUNCTIONS AND OTHER EQUITABLE RELIEF.—In a civil action under subparagraph (A), the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law.

(5) PRESERVATION OF AUTHORITY OF COMMISSION.—Nothing in this section shall be construed to affect any authority of the Commission under any other provision of law.

(e) FEDERAL TRADE COMMISSION RULEMAKING.—The Commission may, in its discretion, by rule promul-

gated under section 553 of title 5, United States Code, exempt from this section certain agreements described in subsection (a) if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers.

(f) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of a subsequent filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

(g) DEFINITIONS.—In this section:

(1) AGREEMENT RESOLVING OR SETTLING A COVERED PATENT INFRINGEMENT CLAIM.—The term "agreement resolving or settling a covered patent infringement claim" means any agreement that—

(A) resolves or settles a covered patent infringement claim; or

(B) is contingent upon, provides for a contingent condition for, or is otherwise related to the resolution or settlement of a covered patent infringement claim.

(2) COMMISSION.—The term "Commission" means the Federal Trade Commission.

(3) COVERED PATENT INFRINGEMENT CLAIM.—The term "covered patent infringement claim" means an allegation made by the NDA or BLA holder to a subsequent filer (or, in the case of an agreement between two subsequent filers, by one subsequent filer to another), whether or not included in a complaint filed with a court of law, that—

(A) the submission of the application described in subparagraph (A) or (B) of paragraph (9), or the manufacture, use, offering for sale, sale, or importation into the United States of a covered product that is the subject of such an application—

(i) in the case of an agreement between an NDA or BLA holder and a subsequent filer, infringes any patent owned by, or exclusively licensed to, the NDA or BLA holder of the covered product; or

(ii) in the case of an agreement between two subsequent filers, infringes any patent owned by the subsequent filer; or

(B) in the case of an agreement between an NDA or BLA holder and a subsequent filer, the covered product to be manufactured under such application uses a covered product as claimed in a published patent application.

(4) COVERED PRODUCT.—The term "covered product" means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) NDA OR BLA HOLDER.—The term "NDA or BLA holder" means—

(A) the holder of—

(i) an approved new drug application filed under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) for a covered product; or

(ii) a biologics license application filed under section 351(a) of the Public Health

Service Act (42 U.S.C. 262(a)) with respect to a biological product;

(B) a person owning or controlling enforcement of the patent on—

(i) the list published under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) in connection with the application described in subparagraph (A)(i); or

(ii) any list published under section 351 of the Public Health Service Act (42 U.S.C. 262) comprised of patents associated with biologics license applications filed under section 351(a) of such Act (42 U.S.C. 262(a)); or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any entity described in subparagraph (A) or (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(6) PATENT.—The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) STATUTORY EXCLUSIVITY.—The term "statutory exclusivity" means those prohibitions on the submission or approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii) through (iv) of section 505(j)(5)(F) (5-year and 3-year exclusivity), section 505(j)(5)(B)(iv) (180-day exclusivity), section 527 (orphan drug exclusivity), section 505A (pediatric exclusivity), or section 505E (qualified infectious disease product exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F), 360cc, 355a, 355f), or prohibitions on the submission or licensing of biologics license applications under section 351(k)(6) (interchangeable biological product exclusivity) or section 351(k)(7) (biological product reference product exclusivity) of the Public Health Service Act (42 U.S.C. 262(k)(6), (7)).

(8) SUBSEQUENT FILER.—The term "subsequent filer" means—

(A) in the case of a drug, a party that owns or controls an abbreviated new drug appli-

cation submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21U.S.C. 355(b)(2)) and filed under section 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or has the exclusive rights to distribute the covered product that is the subject of such application; or

(B) in the case of a biological product, a party that owns or controls an application filed with the Food and Drug Administration under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) or has the exclusive rights to distribute the biological product that is the subject of such application.

(h) EFFECTIVE DATE.—This section applies with respect to agreements described in subsection (a) entered into on or after the date of the enactment of this Act.

SEC. 112. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1111(7) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by inserting "or the owner of a patent for which

a claim of infringement could reasonably be asserted against any person for making, using, offering to sell, selling, or importing into the United States a biological product that is the subject of a biosimilar biological product application'' before the period at the end.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act (21 U.S.C. 355 note) is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement under subsection (a) or (b) that is required to be filed under subsection (c) shall, within 30 days of such filing, execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

'''(1) represent the complete, final, and exclusive agreement between the parties;

'''(2) include any ancillary agreements that are contingent upon, provide a contingent condition for,

were entered into within 30 days of, or are otherwise related to, the referenced agreement; and

"'(3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

SEC. 113. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting "section 111 of the Strengthening Health Care and Lowering Prescription Drug Costs Act or" after "that the agreement has violated".

SEC. 114. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking "or" after the semicolon;

(2) in subparagraph (E), by inserting "or" after the semicolon; and

(3) by inserting after subparagraph (E) the following:

"(F) under section 111(d)(3)(A) of the Strengthening Health Care and Lowering Prescription Drug Costs Act;".

SEC. 115. STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Except as provided in subsection (b), the Commission shall commence any administrative proceeding or civil action to enforce section 111 of this Act not later than 6 years after the date on which the parties to the agreement file the Notice of Agreement as provided by section 1112(c)(2) and (d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note).

(b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND DESIST ORDER.—If the Commission has issued a cease and desist order under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of section 111 of this Act and the proceeding for the issuance of such order was commenced within the period required by subsection (a) of this section, such subsection does not prohibit the commencement, after such period, of a civil action under section 111(d)(3)(A) against a party to such order or a civil action under subsection (l) of such section 5 for violation of such order.

Subtitle C—Creating and Restoring Equal Access to Equivalent Samples

SEC. 121. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''commercially reasonable, market-based terms'' means—

(A) a nondiscriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless—

(i) the drug or biological product has been on the drug shortage list in effect under such section 506E continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage.

(3) the term "device" has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(4) the term "eligible product developer" means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term "license holder" means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

(6) the term "REMS" means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term "REMS with ETASU" means a REMS that contains elements to assure safe use

under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f));

(8) the term "Secretary" means the Secretary of Health and Human Services;

(9) the term "single, shared system of elements to assure safe use" means a single, shared system of elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); and

(10) the term "sufficient quantities" means an amount of a covered product that the eligible product developer determines allows it to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of

the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has submitted a written request to purchase sufficient quantities of the covered product to the license holder and such request—

(I) was sent to a named corporate officer of the license holder;

(II) was made by certified or registered mail with return receipt requested;

(III) specified an individual as the point of contact for the license holder to direct communications related to the sale of the covered product to the eligible product developer and a means for electronic and written communications with that individual; and

(IV) specified an address to which the covered product was to be shipped upon reaching an agreement to transfer the covered product; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization

issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms;

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its

agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to the individual specified pursuant to paragraph (2)(A)(iii)(III), by a means of communication (electronic, written, or both) specified pursuant to such paragraph, to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product devel-

oper received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to

deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under

Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) NO VIOLATION OF REMS.—Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended by adding at the end the following new subsection:

"(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 121(a) of the Strengthening Health Care and Lowering Prescription Drug Costs Act) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under this section for such drug.".

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term "antitrust laws"—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 122. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), as amended by section 121, is further amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking "or" after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 505(j), and the applicable listed drug.";

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:

"(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 505(j) may use—

"(I) a single, shared system with the listed drug under subsection (f); or

"(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

"(ii) The Secretary may require a drug that is the subject of an application under section 505(j) and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).";

(3) in subsection (i), by adding at the end the following:

"(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that

such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug.''; and

(4) by adding at the end the following:

''(m) SEPARATE REMS.—When used in this section, the terms 'different, comparable aspect of the elements to assure safe use' or 'different, comparable approved risk evaluation and mitigation strategies' means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable listed drug, or other application under section 505(j) with the same such listed drug, but achieves the same level of safety as such strategy.''.

SEC. 123. RULE OF CONSTRUCTION.

(a) IN GENERAL.—Nothing in this subtitle, the amendments made by this subtitle, or in section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), shall be construed as—

(1) prohibiting a license holder from providing an eligible product developer access to a covered

product in the absence of an authorization under this subtitle; or

(2) in any way negating the applicability of a REMS with ETASU, as otherwise required under such section 505–1, with respect to such covered product.

(b) DEFINITIONS.—In this section, the terms "covered product", "eligible product developer", "license holder", and "REMS with ETASU" have the meanings given such terms in section 121(a).

Subtitle D—Study on Role of Federal Assistance in Drug Development

SEC. 131. STUDY ON ROLE OF FEDERAL ASSISTANCE IN DRUG DEVELOPMENT.

(a) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Secretary of the Health and Human Services shall enter into a contract with the National Academy of Medicine to conduct a study on, and submit to Congress a report on, the following:

(1) The percentage of drugs developed in the United States using at least some amount of Federal funding from any Federal source.

(2) The average cost incurred by a drug developer to develop a drug.

(3) The average amount of revenue and profits made by drug developers from the sales of drugs.

(4) The percentage of such revenue and profits that are reinvested into research and development of new drugs.

(5) The appropriate percentage, if any, of such revenue and profits the Secretary, in consultation with the National Academy of Medicine, recommends should be returned to Federal entities for Federal funding used in the development of the drugs involved.

(b) ENFORCEMENT.—A drug developer shall, as a condition of receipt of any Federal funding for the development of drugs, comply with any request for the data necessary to perform the study under subsection (a).

(c) CONFIDENTIALITY.—This section does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(d) DEFINITIONS.—In this section:

(1) The term "drug" has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(2) The term "drug developer" means an entity that submitted, and received approval of, an applica-

tion under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

Subtitle E—Pharmacy School Outreach

SEC. 141. PHARMACY SCHOOL OUTREACH.

The Secretary of Health and Human Services and the Secretary of Education shall make every effort necessary to ensure appropriate outreach to institutions of higher education to ensure that students and faculty at schools of pharmacy are provided with materials regarding generic drugs and biosimilar biological products, including materials on—

(1) how generic drugs and biosimilar biological products are equivalent or similar to brand-name drugs;

(2) the approval process at the Food and Drug Administration for generic drugs and biosimilar biological products;

(3) how to make consumers aware of the availability of generic drugs and biosimilar biological products;

(4) requirements for substituting generic drugs and biosimliar biological products in place of corresponding drugs products; and

(5) the impacts of generic drugs and biosimilar biological products on consumer costs.

Subtitle F—Reports

SEC. 151. EFFECTS OF INCREASES IN PRESCRIPTION DRUG PRICE.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Congress on the extent to which increases in prescription drug prices may have caused Medicare beneficiaries to forego recommended treatment, including failing to fill prescriptions.

TITLE II—HEALTH INSURANCE MARKET STABILIZATION

SEC. 201. PRESERVING STATE OPTION TO IMPLEMENT HEALTH CARE MARKETPLACES.

(a) IN GENERAL.—Section 1311 of the Patient Protection and Affordable Care Act (42 U.S.C. 18031) is amended—

(1) in subsection (a)—

(A) in paragraph (4)(B), by striking "under this subsection" and inserting "under this paragraph or paragraph (1)"; and

(B) by adding at the end the following new paragraph:

"(6) ADDITIONAL PLANNING AND ESTABLISHMENT GRANTS.—

"(A) IN GENERAL.—There shall be appropriated to the Secretary, out of any moneys in the Treasury not otherwise appropriated, $200 million to award grants to eligible States for the uses described in paragraph (3).

"(B) DURATION AND RENEWABILITY.—A grant awarded under subparagraph (A) shall be for a period of 2 years and may not be renewed.

"(C) LIMITATION.—A grant may not be awarded under subparagraph (A) after December 31, 2023.

"(D) ELIGIBLE STATE DEFINED.—For purposes of this paragraph, the term 'eligible State' means a State that, as of the date of the enactment of this paragraph, is not operating an Exchange (other than an Exchange described in section 155.200(f) of title 45, Code of Federal Regulations)."; and

(2) in subsection (d)(5)(A)—

(A) by striking "OPERATIONS.—In establishing an Exchange under this section" and inserting "OPERATIONS.—

"(i) IN GENERAL.—In establishing an Exchange under this section (other than in establishing an Exchange pursuant to a grant awarded under subsection (a)(6))"; and

(B) by adding at the end the following:

"(ii) ADDITIONAL PLANNING AND ESTABLISHMENT GRANTS.—In establishing an Exchange pursuant to a grant awarded under subsection (a)(6), the State shall ensure that such Exchange is self-sustaining beginning on January 1, 2025, including allowing the Exchange to charge assessments or user fees to participating health insurance issuers, or to otherwise generate funding, to support its operations.".

(b) CLARIFICATION REGARDING FAILURE TO ESTABLISH EXCHANGE OR IMPLEMENT REQUIREMENTS.—Section 1321(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)) is amended—

(1) in paragraph (1), by striking "If" and inserting "Subject to paragraph (3), if"; and

(2) by adding at the end the following new paragraph:

"(3) CLARIFICATION.—This subsection shall not apply in the case of a State that elects to apply the requirements described in subsection (a) and satisfies the requirement described in subsection (b) on or after January 1, 2014.".

SEC. 202. PROVIDING FOR ADDITIONAL REQUIREMENTS WITH RESPECT TO THE NAVIGATOR PROGRAM.

(a) IN GENERAL.—Section 1311(i) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(i)) is amended—

(1) in paragraph (2), by adding at the end the following new subparagraph:

"(C) SELECTION OF RECIPIENTS.—In the case of an Exchange established and operated by the Secretary within a State pursuant to section 1321(c), in awarding grants under paragraph (1), the Exchange shall—

"(i) select entities to receive such grants based on an entity's demonstrated capacity to carry out each of the duties specified in paragraph (3);

"(ii) not take into account whether or not the entity has demonstrated how the entity will provide information to individ-

uals relating to group health plans offered by a group or association of employers described in section 2510.3–5(b) of title 29, Code of Federal Regulations (or any successor regulation), or short-term limited duration insurance (as defined by the Secretary for purposes of section 2791(b)(5) of the Public Health Service Act); and

"(iii) ensure that, each year, the Exchange awards such a grant to—

"(I) at least one entity described in this paragraph that is a community and consumer-focused nonprofit group; and

"(II) at least one entity described in subparagraph (B), which may include another community and consumer-focused nonprofit group in addition to any such group awarded a grant pursuant to subclause (I).

In awarding such grants, an Exchange may consider an entity's record with respect to waste, fraud, and abuse for purposes of maintaining the integrity of such Exchange.".

(2) in paragraph (3)—

(A) by amending subparagraph (C) to read as follows:

"(C) facilitate enrollment, including with respect to individuals with limited English proficiency and individuals with chronic illnesses, in qualified health plans, State medicaid plans under title XIX of the Social Security Act, and State child health plans under title XXI of such Act;";

(B) in subparagraph (D), by striking "and" at the end;

(C) in subparagraph (E), by striking the period at the end and inserting a semicolon;

(D) by inserting after subparagraph (E) the following:

"(F) conduct public education activities in plain language to raise awareness of the requirements of and the protections provided under—

"(i) the essential health benefits package (as defined in section 1302(a)); and

"(ii) section 2726 of the Public Health Service Act (relating to parity in mental health and substance use disorder benefits); and";

(E) by inserting after subparagraph (F) (as added by subparagraph (D)) the following new subparagraph:

"(G) provide referrals to community-based organizations that address social needs related to health outcomes."; and

(F) by adding at the end the following flush left sentence:

"The duties specified in the preceding sentences may be carried out by such a navigator at any time during a year.";

(3) in paragraph (4)(A)—

(A) in the matter preceding clause (i), by striking "not";

(B) in clause (i)—

(i) by inserting "not" before "be"; and

(ii) by striking "; or" and inserting a semicolon;

(C) in clause (ii)—

(i) by inserting "not" before "receive"; and

(ii) by striking the period and inserting a semicolon; and

(D) by adding at the end the following new clauses:

"(iii) maintain physical presence in the State of the Exchange so as to allow in-person assistance to consumers;

"(iv) receive training on how to assist individuals with enrolling for medical assistance under State plans under the Medicaid program under title XIX of the Social Security Act or for child health assistance under State child health plans under title XXI of such Act; and

"(v) receive opioid specific education and training that ensures the navigator can best educate individuals on qualified health plans offered through an Exchange, specifically coverage under such plans for opioid health care treatment."; and

(4) in paragraph (6)—

(A) by striking "FUNDING.—Grants under" and inserting "FUNDING.—

"(A) STATE EXCHANGES.—Subject to subparagraph (C), grants under"; and

(B) by adding at the end the following new subparagraphs:

"(B) FEDERAL EXCHANGES.—For purposes of carrying out this subsection, with respect to an Exchange established and operated by the Secretary within a State pursuant to section 1321(c), the Secretary shall obligate $100 million out of amounts collected through the user fees on participating health insurance issuers pursuant to section 156.50 of title 45, Code of Federal Regulations (or any successor regulations) for fiscal year 2020 and each subsequent fiscal year. Such amount for a fiscal year shall remain available until expended.

"(C) STATE EXCHANGES.—For the purposes of carrying out this subsection, with respect to an Exchange operated by a State pursuant to this section, there is authorized to be appropriated $25 million for fiscal year 2020 and each subsequent fiscal year. Each State receiving a grant pursuant to this subparagraph shall receive a grant in an amount that is not less than $1 million.".

(b) STUDY ON EFFECTS OF FUNDING CUTS.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall study the effects of funding cuts made for plan year 2019

with respect to the navigator program (as described in section 1311(i) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(i))) and other education and outreach activities carried out with respect to Exchanges established by the Secretary of Health and Human Services pursuant to section 1321(c) of such Act. Such study shall describe the following:

(1) How such funding cuts negatively impacted the ability of entities under such program to conduct outreach activities and fulfill duties required under such section 1311(i).

(2) The overall effect on—

(A) the number of individuals enrolled in health insurance coverage offered in the individual market for plan year 2019; and

(B) the costs of health insurance coverage offered in the individual market.

(c) PROMOTE TRANSPARENCY AND ACCOUNTABILITY IN THE ADMINISTRATION'S EXPENDITURES OF EXCHANGE USER FEES.—For plan year 2020 and each subsequent plan year, not later than the date that is 3 months after the end of such plan year, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress and make available to the public an annual report on the expenditures by the Department of

Health and Human Services of user fees collected pursuant to section 156.50 of title 45, Code of Federal Regulations (or any successor regulations). Each such report for a plan year shall include a detailed accounting of the amount of such user fees collected during such plan year and of the amount of such expenditures used during such plan year for the federally facilitated Exchange operated pursuant to section 1321(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)) on outreach and enrollment activities, navigators, maintenance of Healthcare.gov, and operation of call centers.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2020.

SEC. 203. FEDERAL EXCHANGE OUTREACH AND EDUCATIONAL ACTIVITIES AND ANNUAL ENROLLMENT TARGETS.

(a) IN GENERAL.—Section 1321(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)), as amended by section 201(b)(2), is further amended by adding at the end the following new paragraphs:

"(4) OUTREACH AND EDUCATIONAL ACTIVITIES.—

"(A) IN GENERAL.—In the case of an Exchange established or operated by the Secretary

within a State pursuant to this subsection, the Secretary shall carry out outreach and educational activities for purposes of informing individuals about qualified health plans offered through the Exchange, including by informing such individuals of the availability of coverage under such plans and financial assistance for coverage under such plans. Such outreach and educational activities shall be provided in a manner that is culturally and linguistically appropriate to the needs of the populations being served by the Exchange (including hard-to-reach populations, such as racial and sexual minorities, limited English proficient populations, individuals residing in areas where the unemployment rates exceeds the national average unemployment rate, individuals in rural areas, veterans, and young adults) and shall be provided to populations residing in high health disparity areas (as defined in subparagraph (E)) served by the Exchange, in addition to other populations served by the Exchange.

"(B) LIMITATION ON USE OF FUNDS.—No funds appropriated under this paragraph shall

be used for expenditures for promoting non-ACA compliant health insurance coverage.

"(C) NON-ACA COMPLIANT HEALTH INSURANCE COVERAGE.—For purposes of subparagraph (B):

"(i) The term 'non-ACA compliant health insurance coverage' means health insurance coverage, or a group health plan, that is not a qualified health plan.

"(ii) Such term includes the following:

"(I) An association health plan.

"(II) Short-term limited duration insurance.

"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2020 and each subsequent fiscal year, $100 million to carry out this paragraph. Funds appropriated under this subparagraph shall remain available until expended.

"(E) HIGH HEALTH DISPARITY AREA DEFINED.—For purposes of subparagraph (A), the term 'high health disparity area' means a contiguous geographic area that—

"(i) is located in one census tract or ZIP code;

"(ii) has measurable and documented racial, ethnic, or geographic health disparities;

"(iii) has a low-income population, as demonstrated by—

"(I) average income below 138 percent of the Federal poverty line; or

"(II) a rate of participation in the special supplemental nutrition program under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) that is higher than the national average rate of participation in such program;

"(iv) has poor health outcomes, as demonstrated by—

"(I) lower life expectancy than the national average; or

"(II) a higher percentage of instances of low birth weight than the national average; and

"(v) is part of a Metropolitan Statistical Area identified by the Office of Management and Budget.

"(5) ANNUAL ENROLLMENT TARGETS.—For plan year 2020 and each subsequent plan year, in the case of an Exchange established or operated by the Secretary within a State pursuant to this subsection, the Secretary shall establish annual enrollment targets for such Exchange for such year.".

(b) STUDY AND REPORT.—Not later than 30 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall release to Congress all aggregated documents relating to studies and data sets that were created on or after January 1, 2014, and related to marketing and outreach with respect to qualified health plans offered through Exchanges under title I of the Patient Protection and Affordable Care Act.

SEC. 204. SHORT-TERM LIMITED DURATION INSURANCE RULE PROHIBITION.

(a) FINDINGS.—Congress finds the following:

(1) On August 3, 2018, the Administration issued a final rule entitled "Short-Term, Limited-Duration Insurance" (83 Fed. Reg. 38212).

(2) The final rule dramatically expands the sale and marketing of insurance that—

(A) may discriminate against individuals living with preexisting health conditions, including children with complex medical needs and disabilities and their families;

(B) lacks important financial protections provided by the Patient Protection and Affordable Care Act (Public Law 111–148), including the prohibition of annual and lifetime coverage limits and annual out-of-pocket limits, that may increase the cost of treatment and cause financial hardship to those requiring medical care, including children with complex medical needs and disabilities and their families; and

(C) excludes coverage of essential health benefits including hospitalization, prescription drugs, and other lifesaving care.

(3) The implementation and enforcement of the final rule weakens critical protections for up to 130 million Americans living with preexisting health conditions and may place a large financial burden on those who enroll in short-term limited-duration insurance, which jeopardizes Americans' access to quality, affordable health insurance.

(b) PROHIBITION.—The Secretary of Health and Human Services, the Secretary of the Treasury, and the

Secretary of Labor may not take any action to implement, enforce, or otherwise give effect to the rule entitled "Short-Term, Limited Duration Insurance" (83 Fed. Reg. 38212 (August 3, 2018)), and the Secretaries may not promulgate any substantially similar rule.

SEC. 205. PROTECTION OF HEALTH INSURANCE COVERAGE IN CERTAIN EXCHANGES.

In the case of an Exchange that the Secretary of Health and Human Services operates pursuant to section 1321(c)(1) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)(1)), the Secretary may not implement any process that would terminate the health insurance coverage of an enrollee solely because such enrollee did not actively enroll during the most recent open enrollment period.

SEC. 206. SENSE OF CONGRESS RELATING TO THE PRACTICE OF SILVER LOADING.

It is the sense of Congress that the Secretary of Health and Human Services should not take any action to prohibit or otherwise restrict the practice commonly known as "silver loading" (as described in the rule entitled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020" published on April 25, 2019 (84 Fed. Reg. 17533)).

SEC. 207. CONSUMER OUTREACH, EDUCATION, AND ASSISTANCE.

(a) OPEN ENROLLMENT REPORTS.—For plan year 2020 and each subsequent year, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), in coordination with the Secretary of the Treasury and the Secretary of Labor, shall issue biweekly public reports during the annual open enrollment period on the performance of the Federal Exchange. Each such report shall include a summary, including information on a State-by-State basis where available, of—

(1) the number of unique website visits;

(2) the number of individuals who create an account;

(3) the number of calls to the call center;

(4) the average wait time for callers contacting the call center;

(5) the number of individuals who enroll in a qualified health plan; and

(6) the percentage of individuals who enroll in a qualified health plan through each of—

(A) the website;

(B) the call center;

(C) navigators;

(D) agents and brokers;

(E) the enrollment assistant program;

(F) directly from issuers or web brokers; and

(G) other means.

(b) OPEN ENROLLMENT AFTER ACTION REPORT.—For plan year 2020 and each subsequent year, the Secretary, in coordination with the Secretary of the Treasury and the Secretary of Labor, shall publish an after action report not later than 3 months after the completion of the annual open enrollment period regarding the performance of the Federal Exchange for the applicable plan year. Each such report shall include a summary, including information on a State-by-State basis where available, of—

(1) the open enrollment data reported under subsection (a) for the entirety of the enrollment period; and

(2) activities related to patient navigators described in section 1311(i) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(i)), including—

(A) the performance objectives established by the Secretary for such patient navigators;

(B) the number of consumers enrolled by such a patient navigator;

(C) an assessment of how such patient navigators have met established performance

metrics, including a detailed list of all patient navigators, funding received by patient navigators, and whether established performance objectives of patient navigators were met; and

(D) with respect to the performance objectives described in subparagraph (A)—

(i) whether such objectives assess the full scope of patient navigator responsibilities, including general education, plan selection, and determination of eligibility for tax credits, cost-sharing reductions, or other coverage;

(ii) how the Secretary worked with patient navigators to establish such objectives; and

(iii) how the Secretary adjusted such objectives for case complexity and other contextual factors.

(c) REPORT ON ADVERTISING AND CONSUMER OUTREACH.—Not later than 3 months after the completion of the annual open enrollment period for the 2020 plan year, the Secretary shall issue a report on advertising and outreach to consumers for the open enrollment period for the 2020 plan year. Such report shall include a description of—

(1) the division of spending on individual advertising platforms, including television and radio advertisements and digital media, to raise consumer awareness of open enrollment;

(2) the division of spending on individual outreach platforms, including email and text messages, to raise consumer awareness of open enrollment; and

(3) whether the Secretary conducted targeted outreach to specific demographic groups and geographic areas.

SEC. 208. GAO REPORT.

Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a study that analyzes the costs and benefits of the establishment of State-administered health insurance plans to be offered in the insurance market of such States that choose to administer and offer such a plan.

SEC. 209. REPORT ON THE EFFECTS OF WEBSITE MAINTENANCE DURING OPEN ENROLLMENT.

Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report examining whether the Department of Health and Human Services has been conducting maintenance on the website commonly referred to

as "Healthcare.gov" during annual open enrollment periods (as described in section 1311(c)(6)(B) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(c)(6)(B)) in such a manner so as to minimize any disruption to the use of such website resulting from such maintenance.

TITLE III—BUDGETARY EFFECTS

SEC. 301. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled "Budgetary Effects of PAYGO Legislation" for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

Passed the House of Representatives May 16, 2019.

Attest: CHERYL L. JOHNSON,

Clerk.

IB

Union Calendar No. 29

116TH CONGRESS
1ST SESSION

H. R. 1010

[Report No. 116–43, Parts I and II]

To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 6, 2019

Ms. CASTOR of Florida (for herself, Ms. BARRAGÁN, Mr. HORSFORD, Ms. MOORE, Ms. UNDERWOOD, and Mr. DESAULNIER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Labor, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

APRIL 29, 2019

Reported from the Committee on Education and Labor

MAY 10, 2019

Additional sponsors: Mr. WELCH, Ms. SCHAKOWSKY, Mr. KENNEDY, Mr. RUIZ, Mrs. DINGELL, Mr. RUSH, Mr. PALLONE, Ms. MATSUI, Ms. ESHOO, Ms. CLARKE of New York, Ms. SHALALA, Mr. VAN DREW, Ms. WILD, Ms. MCCOLLUM, Mr. CARBAJAL, Mr. CASE, Mr. GRIJALVA, Mr. MOULTON, Mr. KILMER, Ms. MUCARSEL-POWELL, and Mr. LANGEVIN

MAY 10, 2019

Reported from the Committee on Energy and Commerce

MAY 10, 2019

Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

A BILL

To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT-TERM LIMITED DURATION INSURANCE RULE PROHIBITION.

The Secretary of Health and Human Services, the Secretary of the Treasury, and the Secretary of Labor may not take any action to implement, enforce, or otherwise give effect to the rule entitled "Short-Term, Limited Duration Insurance" (83 Fed. Reg. 38212 (August 3, 2018)), and the Secretaries may not promulgate any substantially similar rule.

Case 4:24-cv-00783-SDJ Document 3-5 Filed 08/29/24 Page 71 of 148 PageID #: 1296

Union Calendar No. 29

116TH CONGRESS
1ST SESSION

H. R. 1010

[Report No. 116–43, Parts I and II]

A BILL

To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect.

MAY 10, 2019

Reported from the Committee on Energy and Commerce

MAY 10, 2019

Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

II

117TH CONGRESS
1ST SESSION

S. 352

To amend the Patient Protection and Affordable Care Act to reduce health care costs and expand health care coverage to more Americans.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 22, 2021

Mr. WARNER introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend the Patient Protection and Affordable Care Act to reduce health care costs and expand health care coverage to more Americans.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Health Care Improvement Act of 2021".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—REDUCING HEALTH CARE COSTS AND PROTECTING PEOPLE WITH PREEXISTING CONDITIONS

Sec. 101. Improving affordability by expanding premium assistance for consumers.
Sec. 102. Expanding affordability for working families to fix the family glitch.
Sec. 103. Establishing a State Health Insurance Affordability and Innovation Fund.
Sec. 104. Rescinding the short-term limited duration insurance regulation.
Sec. 105. Revoking section 1332 guidance and rules.
Sec. 106. Promoting consumer outreach and education.

TITLE II—ENCOURAGING MEDICAID EXPANSION AND STRENGTHENING THE MEDICAID PROGRAM

Sec. 201. Incentivizing Medicaid expansion.
Sec. 202. Reducing the administrative FMAP for nonexpansion States.
Sec. 203. State option to provide 12 months of postpartum Medicaid eligibility.
Sec. 204. Supporting State Medicaid programs through economic downturns.
Sec. 205. State flexibility to use administrative simplification policies for enrollment.

TITLE III—ESTABLISHMENT OF A PUBLIC HEALTH CARE OPTION

Sec. 301. Establishment of health plan.
Sec. 302. Availability of plan.
Sec. 303. Affordability.
Sec. 304. Participating providers.
Sec. 305. Provider payment rates.
Sec. 306. No effect on Medicare benefits or Medicare trust funds.

TITLE IV—FAIR MEDICARE PAYMENTS TO RURAL PROVIDERS

Sec. 401. Ensuring fairness in Medicare hospital payments.

TITLE V—COMMONSENSE COMPETITION AND ACCESS TO HEALTH INSURANCE

Sec. 501. Providing small business health insurance across State lines.
Sec. 502. Report and models.

TITLE VI—EMPOWERING MEDICARE SENIORS TO NEGOTIATE PRESCRIPTION DRUG PRICES

Sec. 601. Authority to negotiate fair prices for Medicare prescription drugs.

TITLE VII—COMMONSENSE REPORTING FOR EMPLOYERS

Sec. 701. Voluntary prospective reporting system.
Sec. 702. Protection of dependent privacy.
Sec. 703. Electronic statements.
Sec. 704. GAO studies.
Sec. 705. Tax compliance.

TITLE I—REDUCING HEALTH CARE COSTS AND PROTECTING PEOPLE WITH PRE-EXISTING CONDITIONS

SEC. 101. IMPROVING AFFORDABILITY BY EXPANDING PREMIUM ASSISTANCE FOR CONSUMERS.

(a) IN GENERAL.—Section 36B(b)(3)(A) of the Internal Revenue Code of 1986 is amended to read as follows:

"(A) APPLICABLE PERCENTAGE.—The applicable percentage for any taxable year shall be the percentage such that the applicable percentage for any taxpayer whose household income is within an income tier specified in the following table shall increase, on a sliding scale in a linear manner, from the initial premium percentage to the final premium percentage specified in such table for such income tier:

"In the case of household income (expressed as a percent of poverty line) within the following income tier:	The initial premium percentage is—	The final premium percentage is—
Up to 150.0 percent	0.0	0.0
150.0 percent up to 200.0 percent	0.0	3.0
200.0 percent up to 250.0 percent	3.0	4.0
250.0 percent up to 300.0 percent	4.0	6.0
300.0 percent up to 400.0 percent	6.0	8.5
400.0 percent and higher	8.5	8.5".

(b) CONFORMING AMENDMENT.—Section 36B(c)(1)(A) of the Internal Revenue Code of 1986 is amended by striking "but does not exceed 400 percent".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2021.

SEC. 102. EXPANDING AFFORDABILITY FOR WORKING FAMILIES TO FIX THE FAMILY GLITCH.

(a) IN GENERAL.—Clause (i) of section 36B(c)(2)(C) of the Internal Revenue Code of 1986 is amended to read as follows:

"(i) COVERAGE MUST BE AFFORDABLE.—

"(I) EMPLOYEES.—An employee shall not be treated as eligible for minimum essential coverage if such coverage consists of an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) and the employee's required contribution (within the meaning of section 5000A(c)(1)(B)) with respect to the plan exceeds 9.5 percent of the employee's household income.

"(II) FAMILY MEMBERS.—An individual who is eligible to enroll in an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) by reason of a relationship the individual bears to the employee shall not be treated as eligible for minimum essential coverage by reason of such eligibility to enroll if the employee's required contribution (within the meaning of section 5000A(e)(1)(B), determined by substituting 'family' for 'self-only') with respect to the plan exceeds 9.5 percent of the employee's household income.".

(b) CONFORMING AMENDMENTS.—

(1) Clause (ii) of section 36B(c)(2)(C) of the Internal Revenue Code of 1986 is amended by striking "Except as provided in clause (iii), an employee" and inserting "An individual".

(2) Clause (iii) of section 36B(c)(2)(C) of such Code is amended by striking "the last sentence of clause (i)" and inserting "clause (i)(II)".

(3) Clause (iv) of section 36B(c)(2)(C) of such Code is amended by striking "the 9.5 percent under

clause (i)(II)" and inserting "the 9.5 percent under clauses (i)(I) and (i)(II)".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2021.

SEC. 103. ESTABLISHING A STATE HEALTH INSURANCE AFFORDABILITY AND INNOVATION FUND.

Subtitle D of title I of the Patient Protection and Affordable Care Act (42 U.S.C. 18021 et seq.) is amended by adding at the end the following:

"PART 6—STATE HEALTH INSURANCE AFFORDABILITY AND INNOVATION FUND

"SEC. 1351. ESTABLISHMENT OF PROGRAM.

"There is hereby established the 'State Health Insurance Affordability and Innovation Fund' to be administered by the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services (referred to in this section as the 'Administrator'), to provide funding, in accordance with this part, to each of the 50 States and the District of Columbia (each referred to in this section as a 'State') beginning on January 1, 2022, for the purposes described in section 1352.

"SEC. 1352. USE OF FUNDS.

"(a) IN GENERAL.—A State shall use the funds allocated to the State under this part for one of the following purposes:

"(1) To provide reinsurance payments to health insurance issuers with respect to individuals enrolled under individual health insurance coverage (other than through a plan described in subsection (b)) offered by such issuers.

"(2) To provide assistance (other than through payments described in paragraph (1)) to reduce out-of-pocket costs, such as copayments, coinsurance, premiums, and deductibles, of individuals enrolled under qualified health plans offered on the individual market through an Exchange.

"(3) State efforts to streamline health insurance enrollment procedures in order to reduce burdens on consumers and facilitate greater enrollment in health insurance coverage in the individual and small group markets, including automatic enrollment and reenrollment of, or pre-populated applications for, individuals without health insurance who are eligible for tax credits under section 36B of the Internal Revenue Code of 1986, with the ability to opt out of such enrollment.

"(4) State investment in technology to improve data sharing and collection for the purposes of facilitating greater enrollment in health insurance coverage in such markets.

"(5) Feasibility studies to develop a comprehensive and coherent State plan for increasing enrollment in the individual and small group market.

"(b) EXCLUSION OF CERTAIN GRANDFATHERED AND TRANSITIONAL PLANS.—For purposes of subsection (a), a plan described in this subsection is the following:

"(1) A grandfathered health plan (as defined in section 1251).

"(2) A plan (commonly referred to as a 'transitional plan') continued under the letter issued by the Centers for Medicare & Medicaid Services on November 14, 2013, to the State Insurance Commissioners outlining a transitional policy for coverage in the individual and small group markets to which section 1251 does not apply, and under the extension of the transitional policy for such coverage set forth in the Insurance Standards Bulletin Series guidance issued by the Centers for Medicare & Medicaid Services on March 5, 2014, February 29, 2016, February 13, 2017, April 9, 2018, March 25, 2019, and

January 31, 2020, or under any subsequent extensions thereof.

"(3) Student health insurance coverage (as defined in section 147.145 of title 45, Code of Federal Regulations).

"SEC. 1353. STATE ELIGIBILITY AND APPROVAL; DEFAULT SAFEGUARD.

"(a) ENCOURAGING STATE OPTIONS FOR ALLOCATIONS.—

"(1) IN GENERAL.—To be eligible for an allocation of funds under this part for a year (beginning with 2022), a State shall submit to the Administrator an application at such time (but, in the case of allocations for 2022, not later than 90 days after the date of the enactment of this part and, in the case of allocations for a subsequent year, not later than March 1 of the previous year) and in such form and manner as specified by the Administrator containing—

"(A) a description of how the funds will be used; and

"(B) such other information as the Administrator may require.

"(2) AUTOMATIC APPROVAL.—An application so submitted is approved unless the Administrator noti-

fies the State submitting the application, not later than 60 days after the date of the submission of such application, that the application has been denied for not being in compliance with any requirement of this part and of the reason for such denial.

"(3) 5-YEAR APPLICATION APPROVAL.—If an application of a State is approved for a purpose described in section 1352 for a year, such application shall be treated as approved for such purpose for each of the subsequent 4 years.

"(4) REVOCATION OF APPROVAL.—The approval of an application of a State, with respect to a purpose described in section 1352, may be revoked if the State fails to use funds provided to the State under this section for such purpose or otherwise fails to comply with the requirements of this section.

"(b) DEFAULT FEDERAL SAFEGUARD.—

"(1) 2022.—For 2022, in the case of a State that does not submit an application under subsection (a) by the 90-day submission date applicable to such year under subsection (a)(1) and in the case of a State that does submit such an application by such date that is not approved, the Administrator, in consultation with the State insurance commissioner, shall, from the amount calculated under paragraph

(4) for such year, carry out the purpose described in paragraph (3) in such State for such year.

"(2) 2023 AND SUBSEQUENT YEARS.—For 2023 or a subsequent year, in the case of a State that does not have in effect an approved application under this section for such year, the Administrator, in consultation with the State insurance commissioner, shall, from the amount calculated under paragraph (4) for such year, carry out the purpose described in paragraph (3) in such State for such year.

"(3) SPECIFIED USE.—The amount described in paragraph (4), with respect to 2022 or a subsequent year, shall be used to carry out the purpose described in section 1352(a)(1) in each State described in paragraph (1) or (2) for such year, as applicable, by providing reinsurance payments to health insurance issuers with respect to attachment range claims (as defined in section 1354(b)(2)), using the dollar amounts specified in subparagraph (B) of such section for such year in an amount equal to, subject to paragraph (5), the percentage (specified for such year by the Secretary under such subparagraph) of the amount of such claims.

"(4) AMOUNT DESCRIBED.—The amount described in this paragraph, with respect to 2022 or a subsequent year, is the amount equal to the total sum of amounts that the Secretary would otherwise estimate under section 1354(b)(2)(A)(i) for such year for each State described in paragraph (1) or (2) for such year, as applicable, if each such State were not so described for such year.

"(5) ADJUSTMENT.—For purposes of this subsection, the Secretary may apply a percentage under paragraph (3) with respect to a year that is less than the percentage otherwise specified in section 1354(b)(2)(B) for such year, if the cost of paying the total eligible attachment range claims for States described in this subsection for such year at such percentage otherwise specified would exceed the amount calculated under paragraph (4) for such year.

"SEC. 1354. ALLOCATIONS.

"(a) APPROPRIATION.—For the purpose of providing allocations for States under subsection (b) and payments under section 1353(b), there is appropriated, out of any money in the Treasury not otherwise appropriated, $10,000,000,000 for 2022 and each subsequent year.

"(b) ALLOCATIONS.—

"(1) PAYMENT.—

"(A) IN GENERAL.—From amounts appropriated under subsection (a) for a year, the Secretary shall, with respect to a State not described in section 1353(b) for such year and not later than the date specified under subparagraph (B) for such year, allocate for such State the amount determined for such State and year under paragraph (2).

"(B) SPECIFIED DATE.—For purposes of subparagraph (A), the date specified in this subparagraph is—

"(i) for 2022, the date that is 45 days after the date of the enactment of this part; and

"(ii) for 2023 or a subsequent year, January 1 of the respective year.

"(C) NOTIFICATIONS OF ALLOCATION AMOUNTS.—For 2023 and each subsequent year, the Secretary shall notify each State of the amount determined for such State under paragraph (2) for such year by not later than January 1 of the previous year.

"(2) ALLOCATION AMOUNT DETERMINATIONS.—

"(A) IN GENERAL.—For purposes of paragraph (1), the amount determined under this paragraph for a year for a State described in paragraph (1)(A) for such year is the amount equal to—

"(i) the amount that the Secretary estimates would be expended under this part for such year on attachment range claims of individuals residing in such State if such State used such funds only for the purpose described in paragraph (1) of section 1352(a) at the dollar amounts and percentage specified under subparagraph (B) for such year; minus

"(ii) the amount, if any, by which the Secretary determines—

"(I) the estimated amount of premium tax credits under section 36B of the Internal Revenue Code of 1986 that would be attributable to individuals residing in such State for such year without application of this part; exceeds

"(II) the estimated amount of premium tax credits under section

36B of the Internal Revenue Code of 1986 that would be attributable to individuals residing in such State for such year if such State were a State described in section 1353(b) for such year.

For purposes of the previous sentence and section 1353(b)(3), the term 'attachment range claims' means, with respect to an individual, the claims for such individual that exceed a dollar amount specified by the Secretary for a year, but do not exceed a ceiling dollar amount specified by the Secretary for such year, under subparagraph (B).

"(B) SPECIFICATIONS.—For purposes of subparagraph (A) and section 1353(b)(3), the Secretary shall determine the dollar amounts and the percentage to be specified under this subparagraph for a year in a manner to ensure that the total amount of expenditures under this part for such year is estimated to equal the total amount appropriated for such year under subsection (a) if such expenditures were used solely for the purpose described in paragraph (1) of section 1352(a) for attachment range

claims at the dollar amounts and percentage so specified for such year.

"(3) AVAILABILITY.—Funds allocated to a State under this subsection for a year shall remain available through the end of the subsequent year.".

SEC. 104. RESCINDING THE SHORT-TERM LIMITED DURATION INSURANCE REGULATION.

The Secretary of Health and Human Services, the Secretary of the Treasury, and the Secretary of Labor—

(1) may not take any action to implement, enforce, or otherwise give effect to the rule entitled "Short-Term, Limited Duration Insurance" (83 Fed. Reg. 38212 (August 3, 2018));

(2) shall apply any regulation revised by such rule as if such rule had not been issued; and

(3) may not promulgate any substantially similar rule.

SEC. 105. REVOKING SECTION 1332 GUIDANCE AND RULES.

(a) PROVIDING THAT CERTAIN GUIDANCE AND RULES RELATED TO WAIVERS FOR STATE INNOVATION UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT SHALL HAVE NO FORCE OR EFFECT.—The Secretary of Health and Human Services and the Secretary of the Treasury may not—

(1) take any action to implement, enforce, or otherwise give effect to the guidance entitled "State Relief and Empowerment Waivers" (83 Fed. Reg. 53575 (October 24, 2018)), or any rule promulgated to give effect to such guidance, including any such action that would—

(A) result in individuals losing health insurance coverage that includes the essential health benefits package (as defined in subsection (a) of section 1302 of the Patient Protection and Affordable Care Act (42 U.S.C. 18022) without regard to any waiver of any provision of such package under a waiver under section 1332 of such Act (42 U.S.C. 18052)), including the maternity and newborn care essential health benefit described in subsection (b)(1)(D) of such section 1302;

(B) result in a decrease in the number of such individuals enrolled in coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) compared to the number of such individuals who would have been so enrolled in such coverage had such action not been taken;

(C) with respect to individuals with substance use disorders, including opioid use disorders, reduce the availability or affordability of coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) compared to the availability or affordability, respectively, of such coverage had such action not been taken;

(D) result, with respect to vulnerable populations (including low-income individuals, elderly individuals, and individuals with serious health issues or who have a greater risk of developing serious health issues), in a decrease in the availability of coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) with coverage and cost-sharing protections required under section 1332(b)(1)(B) of such Act (42 U.S.C. 18052(b)(1)(B));

(E) with respect to individuals with preexisting conditions, reduce the affordability of coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the

Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) compared to the affordability of such coverage had such action not been taken; or

(F) result in higher health insurance premiums for individuals enrolled in health insurance coverage that is at least as comprehensive as the coverage defined in section 1302(b) of such Act (42 U.S.C. 18022(b)); or

(2) promulgate any substantially similar guidance or rule.

(b) RULE OF CONSTRUCTION.—Nothing in subsection (a) shall be construed to affect the approval of waivers under section 1332 of the Patient Protection and Affordable Care Act (42 U.S.C. 18052) that establish reinsurance programs that are consistent with the requirements under subsection (b)(1) of such section (42 U.S.C. 18052(b)(1)), lower health insurance premiums, and protect health insurance coverage for people with preexisting conditions.

SEC. 106. PROMOTING CONSUMER OUTREACH AND EDUCATION.

(a) IN GENERAL.—Section 1311(i) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(i)) is amended—

(1) in paragraph (2), by adding at the end the following new subparagraph:

"(C) SELECTION OF RECIPIENTS.—In the case of an Exchange established and operated by the Secretary within a State pursuant to section 1321(c), in awarding grants under paragraph (1), the Exchange shall—

"(i) select entities to receive such grants based on an entity's demonstrated capacity to carry out each of the duties specified in paragraph (3);

"(ii) not take into account whether or not the entity has demonstrated how the entity will provide information to individuals relating to group health plans offered by a group or association of employers described in section 2510.3–5(b) of title 29, Code of Federal Regulations (or any successor regulation), or short-term limited duration insurance (as defined by the Secretary for purposes of section 2791(b)(5) of the Public Health Service Act); and

"(iii) ensure that, each year, the Exchange awards such a grant to—

"(I) at least one entity described in this paragraph that is a community and consumer-focused nonprofit group; and

"(II) at least one entity described in subparagraph (B), which may include another community and consumer-focused nonprofit group in addition to any such group awarded a grant pursuant to subclause (I).

In awarding such grants, an Exchange may consider an entity's record with respect to waste, fraud, and abuse for purposes of maintaining the integrity of such Exchange.";

(2) in paragraph (3)—

(A) by amending subparagraph (C) to read as follows:

"(C) facilitate enrollment, including with respect to individuals with limited English proficiency and individuals with chronic illnesses, in qualified health plans, State Medicaid plans under title XIX of the Social Security Act, and State child health plans under title XXI of such Act;";

(B) in subparagraph (D), by striking "and" at the end;

(C) in subparagraph (E), by striking the period at the end and inserting "; and";

(D) by inserting after subparagraph (E) the following new subparagraph:

"(F) provide referrals to community-based organizations that address social needs related to health outcomes."; and

(E) by adding at the end the following flush text:

"The duties specified in the preceding sentence may be carried out by such a navigator at any time during a year.";

(3) in paragraph (4)(A)—

(A) in the matter preceding clause (i), by striking "not";

(B) in clause (i)—

(i) by inserting "not" before "be"; and

(ii) by striking "; or" and inserting a semicolon;

(C) in clause (ii)—

(i) by inserting "not" before "receive"; and

(ii) by striking the period and inserting a semicolon; and

(D) by adding at the end the following new clauses:

"(iii) maintain physical presence in the State of the Exchange so as to allow in-person assistance to consumers; and

"(iv) receive opioid specific education and training that ensures the navigator can best educate individuals on qualified health plans offered through an Exchange, specifically coverage under such plans for opioid health care treatment."; and

(4) in paragraph (6)—

(A) by striking "Grants under" and inserting the following:

"(A) STATE EXCHANGES.—Grants under"; and

(B) by adding at the end the following new subparagraph:

"(B) FEDERAL EXCHANGES.—For purposes of carrying out this subsection, with respect to an Exchange established and operated by the Secretary within a State pursuant to section 1321(c), the Secretary shall obligate

$100,000,000 out of amounts collected through the user fees on participating health insurance issuers pursuant to section 156.50 of title 45, Code of Federal Regulations (or any successor regulations), for fiscal year 2022 and each subsequent fiscal year. Such amount for a fiscal year shall remain available until expended.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2022.

TITLE II—ENCOURAGING MEDICAID EXPANSION AND STRENGTHENING THE MEDICAID PROGRAM

SEC. 201. INCENTIVIZING MEDICAID EXPANSION.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d(y)(1)) is amended—

(1) in subsection (y)(1)—

(A) in subparagraph (A), by striking "2014, 2015, and 2016" and inserting "each of the first 3 consecutive 12-month periods in which the State provides medical assistance to newly eligible individuals";

(B) in subparagraph (B), by striking "2017" and inserting "the fourth consecutive

12-month period in which the State provides medical assistance to newly eligible individuals";

(C) in subparagraph (C), by striking "2018" and inserting "the fifth consecutive 12-month period in which the State provides medical assistance to newly eligible individuals";

(D) in subparagraph (D), by striking "2019" and inserting "the sixth consecutive 12-month period in which the State provides medical assistance to newly eligible individuals"; and

(E) in subparagraph (E), by striking "2020 and each year thereafter" and inserting "the seventh consecutive 12-month period in which the State provides medical assistance to newly eligible individuals and each such period thereafter"; and

(2) in subsection (z)(2)(B)(i)(II), by inserting "(as in effect on the day before the date of enactment of the Health Care Improvement Act of 2021)" after "subsection (y)(1)".

(b) RETROACTIVE APPLICATION.—The amendments made by subsection (a)(1) shall take effect as if included in the enactment of Public Law 111–148 and shall apply to amounts expended by any State for medical assistance

for newly eligible individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) of the Social Security Act under a State Medicaid plan (or a waiver of such plan) during the period before the date of enactment of this Act.

SEC. 202. REDUCING THE ADMINISTRATIVE FMAP FOR NONEXPANSION STATES.

Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended—

(1) in subsection (a)(7), by inserting "subsection (cc) and" before "section 1919(g)(3)(B)"; and

(2) by adding at the end the following new subsection:

"(cc) REDUCTION OF FEDERAL PAYMENTS FOR CERTAIN ADMINISTRATIVE COSTS OF NONEXPANSION STATES.—

"(1) IN GENERAL.—In the case of a State that does not provide under the State plan of such State (or waiver of such plan) for making medical assistance available in accordance with section 1902(k)(1) to all individuals described in section 1902(a)(10)(i)(VIII) for a calendar quarter beginning on or after October 1, 2022, the Secretary may reduce the percentage specified in subsection (a)(7) for amounts described in such subsection expended

during such quarter by such State by the number of percentage points specified in paragraph (2) for such quarter.

"(2) AMOUNT OF REDUCTION.—For purposes of paragraph (1), the number of percentage points specified in this paragraph for a calendar quarter is the following:

"(A) For the calendar quarter beginning on October 1, 2022, 0.5.

"(B) For a calendar quarter beginning on or after January 1, 2023, and ending before July 1, 2027, the number of percentage points specified under this paragraph for the previous quarter, plus 0.5.

"(C) For a calendar quarter beginning on or after July 1, 2027, 10.

"(3) DEFINITION.—For purposes of this subsection, the term 'State' means a State that is one of the 50 States or the District of Columbia.".

SEC. 203. STATE OPTION TO PROVIDE 12 MONTHS OF POSTPARTUM MEDICAID ELIGIBILITY.

(a) OPTION TO PROVIDE CONTINUOUS MEDICAID AND CHIP COVERAGE FOR PREGNANT AND POSTPARTUM WOMEN.—

(1) MEDICAID.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended—

(A) in section 1902(l)(1)(A), by inserting "(or, at the option of the State, 365-day period)" after "60-day period";

(B) in section 1902(e)(6), by inserting "(or, at the option of the State, 365-day period)" after "60-day period";

(C) in section 1903(v)(4)(A)(i), by inserting "(or, at the option of the State, 365-day period)" after "60-day period"; and

(D) in section 1905(a), in the 4th sentence in the matter following paragraph (30), by inserting "(or, at the option of the State, 365-day period)" after "60-day period".

(2) CHIP.—Section 2112 of the Social Security Act (42 U.S.C. 1397ll) is amended by inserting "(or, at the option of the State, 365-day period)" after "60-day period" each place it appears.

(b) REQUIRING FULL BENEFITS FOR PREGNANT AND POSTPARTUM WOMEN.—

(1) MEDICAID.—

(A) IN GENERAL.—Paragraph (5) of section 1902(e) of the Social Security Act (24 U.S.C. 1396a(e)) is amended to read as follows:

"(5) Any woman who is eligible for medical assistance under the State plan or a waiver of such plan and who is, or who while so eligible becomes, pregnant, shall continue to be eligible under the plan or waiver for medical assistance through the end of the month in which the 60-day period (or, at the option of the State, 365-day period) (beginning on the last day of her pregnancy) ends, regardless of the basis for the woman's eligibility for medical assistance, including if the woman's eligibility for medical assistance is on the basis of being pregnant.".

(B) CONFORMING AMENDMENT.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended in the matter following subparagraph (G) by striking "(VII) the medical assistance" and all that follows through "complicate pregnancy,".

(2) CHIP.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

(A) by redesignating subparagraphs (H) through (S) as subparagraphs (I) through (T), respectively; and

(B) by inserting after subparagraph (G), the following:

"(H) Section 1902(e)(5) (requiring 60-day (or, at the option of the State, 365-day) continuous coverage for pregnant and postpartum women).".

(c) MAINTENANCE OF EFFORT.—

(1) MEDICAID.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—

(A) in paragraph (74), by striking "subsection (gg); and" and inserting "subsections (gg) and (tt);"; and

(B) by adding at the end the following new subsection:

"(tt) MAINTENANCE OF EFFORT RELATED TO LOW-INCOME PREGNANT WOMEN.—For calendar quarters beginning on or after the effective date described in section 204(d) of the Health Care Improvement Act of 2021, and before January 1, 2023, no Federal payment shall be made to a State under section 1903(a) for amounts expended under a State plan under this title or a waiver of such plan if the State—

"(1) has in effect under such plan eligibility standards, methodologies, or procedures for individuals described in subsection (l)(1) who are eligible for medical assistance under the State plan or waiver under subsection (a)(10)(A)(ii)(IX) that are more

restrictive than the eligibility standards, methodologies, or procedures, respectively, for such individuals under such plan or waiver that are in effect on the date of the enactment of this subsection; or

"(2) provides medical assistance to individuals described in subsection (l)(1) who are eligible for medical assistance under such plan or waiver under subsection (a)(10)(A)(ii)(IX) at a level that is less than the level at which the State provides such assistance to such individuals under such plan or waiver on the date of the enactment of this subsection.".

(2) CHIP.—Section 2112 of the Social Security Act (42 U.S.C. 1397ll), as amended by subsection (b), is further amended by adding at the end the following subsection:

"(g) MAINTENANCE OF EFFORT.—For calendar quarters beginning on or after the effective date described in section 204(d) of the Health Care Improvement Act of 2021, and before January 1, 2023, no payment may be made under section 2105(a) with respect to a State child health plan if the State—

"(1) has in effect under such plan eligibility standards, methodologies, or procedures for targeted low-income pregnant women that are more restrictive than the eligibility standards, methodologies, or

procedures, respectively, under such plan that are in effect on the date of the enactment of this subsection; or

"(2) provides pregnancy-related assistance to targeted low-income pregnant women under such plan at a level that is less than the level at which the State provides such assistance to such women under such plan on the date of the enactment of this subsection.".

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided under paragraph (2), the amendments made by subsections (a) and (b) shall take effect on (and the effective date described in this subsection shall be) the first day of the first calendar year that begins after the last day of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)).

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX or State child health plan under title XXI of the Social Security Act (42 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.) which the Secretary of Health and Human Services determines requires State legislation (other than leg-

islation appropriating funds) in order for the respective plan to meet the additional requirement imposed by the amendments made by subsection (b), the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such applicable additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

SEC. 204. SUPPORTING STATE MEDICAID PROGRAMS THROUGH ECONOMIC DOWNTURNS.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended—

(1) in subsection (b), by striking "and (ff)" and inserting "(ff), and (hh)"; and

(2) by adding at the end the following new subsection:

"(hh) INCREASED FMAP DURING ECONOMIC DOWNTURNS.—

"(1) IN GENERAL.—If a fiscal quarter that begins on or after January 1, 2021, is an economic downturn quarter (as defined in paragraph (2)) with respect to a State, then the Federal medical assistance percentage determined for each State for such quarter under subsection (b) shall be equal to the percentage determined for the State and quarter under paragraph (3).

"(2) ECONOMIC DOWNTURN QUARTER.—

"(A) IN GENERAL.—

"(i) IN GENERAL.—In this subsection, the term 'economic downturn quarter' means, with respect to a State, a fiscal quarter during which the State's unemployment rate for the quarter exceeds the percentage determined for the State and quarter under clause (ii).

"(ii) THRESHOLD PERCENTAGE.—The percentage determined under this clause for a State and fiscal quarter is the percentage equal to the lower of—

"(I) the State unemployment rate at the 20th percentile of the distribution of the State's quarterly unemployment rates for the 60-quarter

period preceding the quarter involved, increased by 1 percentage point; and

"(II) the State's average quarterly unemployment rate for the 12-quarter period preceding the quarter involved, increased by 1 percentage point.

"(B) UNEMPLOYMENT DATA.—

"(i) IN GENERAL.—Except as provided in clause (ii), for purposes of determining unemployment rates for a State and a quarter under this paragraph, the Secretary shall use data from the Local Area Unemployment Statistics from the Bureau of Labor Statistics.

"(ii) APPLICATION TO CERTAIN TERRITORIES.—In the case of the Virgin Islands, Guam, the Northern Mariana Islands, American Samoa, or any other jurisdiction for which suitable data from the Local Area Unemployment Statistics from the Bureau of Labor Statistics are unavailable, the Secretary shall use data from the U–3 unemployment measure of the Bureau

of Labor Statistics to make any necessary determinations under subparagraph (A).

"(3) INCREASED FMAP DURING ECONOMIC DOWNTURN QUARTER.—

"(A) IN GENERAL.—During a fiscal quarter that is an economic downturn quarter with respect to a State, the Federal medical assistance percentage for the State and quarter determined under subsection (b) shall be equal to—

"(i) the Federal medical assistance percentage determined for the State and quarter under subsection (b) without regard to this subsection (but including any increase to such percentage for such quarter made pursuant to section 6008(a) of the Families First Coronavirus Response Act); increased by

"(ii) the number of percentage points (rounded to the nearest tenth of a percentage point) equal to the product of—

"(I) the number of percentage points (rounded to the nearest tenth of a percentage point) by which the unemployment rate for the State and

quarter exceeds the percentage determined for the State and quarter under paragraph (2)(A)(ii); and

"(II) 4.8.

"(B) RULES OF APPLICATION.—The following rules shall apply with respect to the Federal medical assistance percentage determined for a State and an economic downturn quarter under this subsection:

"(i) SCOPE OF APPLICATION.—Such Federal medical assistance percentage shall not apply for purposes of—

"(I) disproportionate share hospital payments described in section 1923;

"(II) payments under part D of title IV; or

"(III) any payments under this title that are based on a Federal medical assistance percentage determined for a State under subsection (aa) (but only to the extent that such Federal medical assistance percentage is higher than the economic recovery FMAP).

"(ii) LIMITATION.—In no case shall—

"(I) the Federal medical assistance percentage determined for a State and quarter pursuant to this subsection exceed 95 percent; or

"(II) any increase to the Federal medical assistance percentage determined for a State and quarter pursuant to this subsection result in the application of a Federal medical assistance percentage that exceeds 95 percent.

"(iii) APPLICATION TO CHIP.—Notwithstanding the first sentence of section 2105(b), the application of this subsection may result in the enhanced FMAP of a State for a fiscal year under such section exceeding 85 percent, but in no case may the application of this subsection before application of the second sentence of such section result in the enhanced FMAP of the State exceeding 95 percent.

"(4) ADVANCE PAYMENT; RETROSPECTIVE ADJUSTMENT.—

"(A) IN GENERAL.—Prior to the beginning of the second fiscal quarter that begins after the date of enactment of this subsection, and each subsequent fiscal quarter, the Secretary shall, with respect to each State—

"(i) make an initial determination, based on the projections made for the State and quarter under subparagraph (B), as to—

"(I) whether the application of this subsection is expected to result in the application of a higher Federal medical assistance percentage for the State and quarter than the percentage that would otherwise apply without regard to this subsection; and

"(II) if the application of this subsection is expected to result in such a higher Federal medical assistance percentage for the State and quarter, what such higher percentage is expected to be; and

"(ii) if the Secretary determines under clause (i) that the application of this subsection is expected to result in the applica-

tion of a higher Federal medical assistance percentage for the State and quarter than the percentage that would otherwise apply without regard to this subsection—

"(I) apply such higher Federal medical assistance percentage of the State for purposes of making payments to the State for amounts expended during such quarter as medical assistance under the State plan; and

"(II) take into account such higher Federal medical assistance percentage of the State for purposes of calculating the enhanced FMAP for the State and quarter under section 2105(b).

"(B) PROJECTION OF STATE UNEMPLOYMENT RATES.—Prior to the beginning of the second fiscal quarter that begins after the date of enactment of this subsection, and each subsequent fiscal quarter, the Secretary, acting through the Chief Actuary of the Centers for Medicare & Medicaid Services, shall, using the most recently available data described in para-

graph (2)(B), make projections with respect to—

"(i) the unemployment rates for each State for such quarter;

"(ii) the threshold percentages described in paragraph (2)(A)(ii) for each State for such quarter; and

"(iii) the national unemployment rate for such quarter.

"(C) RETROSPECTIVE ADJUSTMENT.—As soon as practicable after final unemployment data becomes available for a fiscal quarter for which the Secretary made an initial determination under this paragraph, the Secretary shall, with respect to each State—

"(i) make a final determination with respect to the application of this subsection for purposes of determining the Federal medical assistance percentage and enhanced FMAP of the State for the quarter; and

"(ii) in accordance with section 1903(d)(2) and section 2105(c), reduce or increase the amount payable to the State under section 1903(a) or section 2105 for

a subsequent fiscal quarter to the extent of any overpayment or underpayment under either such section which the Secretary determines was made as a result of an incorrect initial determination under subparagraph (A)(i) with respect to the application of this subsection for purposes of determining the Federal medical assistance percentage and enhanced FMAP of the State for such prior fiscal quarter.

"(5) RETROSPECTIVE APPLICATION OF OVER-THE-LIMIT FMAP INCREASES.—

"(A) IN GENERAL.—If a State has excess percentage points with respect to an economic downturn quarter and an applicable FMAP (as determined under subparagraph (B)), the State may elect to apply such excess percentage points to increase such applicable FMAP for one or more quarters during the look-back period for the State and economic downturn quarter in accordance with this paragraph.

"(B) EXCESS PERCENTAGE POINTS.—For purposes of this paragraph, the number of excess percentage points for a State, economic downturn quarter, and an applicable FMAP

shall be equal to the number of percentage points by which—

"(i) the applicable FMAP for the State and quarter (after application of paragraph (3) but without regard to subparagraph (B)(ii) of such paragraph); exceeds

"(ii) 95 percent.

"(C) EFFECT OF APPLICATION OF EXCESS PERCENTAGE POINTS.—If a State elects to apply excess percentage points to an applicable FMAP to a quarter during a look-back period under this paragraph, the Secretary shall determine the additional amount of payment under section 1903(a) to which the State would have been entitled for such quarter if the applicable FMAP (as so increased) had been in effect for such quarter, and shall treat such additional amount as an underpayment for such quarter.

"(D) DISTRIBUTION OF EXCESS PERCENTAGE POINTS.—A State that has excess percentage points with respect to an economic downturn quarter and applicable FMAP may elect to divide such points among more than 1 quarter during the look-back period for such State and

quarter provided that no excess percentage point (or fraction of an excess percentage point) is applied to the applicable FMAP of more than 1 quarter.

"(E) LIMITATIONS.—

"(i) NO INCREASES OVER 100 PERCENT.—A State may not increase an applicable FMAP for any quarter during a look-back period under this paragraph if such increase would result in the applicable FMAP for such quarter exceeding 100 percent.

"(ii) SCOPE OF APPLICATION.—Any increase to an applicable FMAP of a State for a fiscal quarter under this paragraph—

"(I) shall only apply with respect to payments for amounts expended by the State for medical assistance for services furnished during such quarter to which such applicable FMAP is applicable; and

"(II) shall not apply with respect to payments described in paragraph (3)(B)(i).

"(F) DEFINITIONS.—In this paragraph:

"(i) APPLICABLE FMAP.—The term 'applicable FMAP' means, with respect to a State and fiscal quarter—

"(I) the Federal medical assistance percentage determined for the State and quarter under subsection (b);

"(II) the Federal medical assistance percentage applicable under subsection (y);

"(III) the Federal medical assistance percentage applicable under subsection (z)(2);

"(IV) the Federal medical assistance percentage determined for the State and quarter under subsection (ff); or

"(V) the enhanced FMAP determined for the State and quarter under section 2105(b).

"(ii) LOOK-BACK PERIOD.—The term 'look-back period' means, with respect to a State and a fiscal quarter that is an economic downturn quarter for the State, the period of 4 fiscal quarters that ends with

the fourth quarter which precedes the most recent fiscal quarters that was not an economic downturn quarter for the State.

"(6) REQUIREMENT FOR ALL STATES.—This subsection shall not apply to a State with respect to a fiscal quarter, if—

"(A) eligibility standards, methodologies, or procedures under the State plan or a waiver of such plan are more restrictive during such quarter than the eligibility standards, methodologies, or procedures, respectively, under such plan (or waiver) as in effect on the last day of the most recent fiscal quarter that was not an economic downturn quarter for the State;

"(B) the amount of any premium imposed by the State pursuant to section 1916 or 1916A during such quarter, with respect to an individual enrolled under such plan (or waiver), exceeds the amount of such premium as of the date described in subparagraph (A); or

"(C) the State fails to provide that an individual who is enrolled for benefits under such plan (or waiver) as of the date described in subparagraph (A) or enrolls for benefits under

such plan (or waiver) during the period beginning with such date and ending with the day before the first day of the next quarter that is not an economic downturn quarter for the State shall be treated as eligible for such benefits for not less than 12 months after such date or (if later) the date that such individual so enrolls unless the individual requests a voluntary termination of eligibility or the individual ceases to be a resident of the State.".

(b) EXCLUSION OF ECONOMIC DOWNTURN FMAP INCREASES FROM TERRITORIAL CAPS; SPECIAL RULE FOR CHIP ALLOTMENTS.—

(1) EXCLUSION FROM TERRITORIAL CAPS.—Section 1108 of the Social Security Act (42 U.S.C. 1308) is amended—

(A) in subsection (f), in the matter preceding paragraph (1), by striking "subsections (g) and (h)" and inserting "subsections (g), (h), and (i)"; and

(B) by adding at the end the following:

"(i) EXCLUSION FROM CAPS OF AMOUNTS ATTRIBUTABLE TO ECONOMIC DOWNTURN FMAP.—Any payment made to a territory for a fiscal year in which the Federal medical assistance percentage for the territory is

determined under section 1905(hh) shall not be taken into account for purposes of applying payment limits under subsections (f) and (g) to the extent that such payment exceeds the amount of the payment that would have been made to the territory for the year if the Federal medical assistance percentage for the territory had been determined without regard to such section.".

(2) CHIP ALLOTMENTS.—Section 2104(m) of the Social Security Act (42 U.S.C. 1397dd(m)) is amended—

(A) in paragraph (2)(B), in the matter preceding clause (i), by striking "paragraphs (5) and (7)" and inserting "paragraphs (5), (7), and (12)"; and

(B) by adding at the end the following new paragraph:

"(12) SPECIAL RULE FOR ADJUSTING ALLOTMENTS DURING FISCAL YEARS WITH ECONOMIC DOWNTURN QUARTERS.—

"(A) IN GENERAL.—If a fiscal quarter is determined under section 1905(hh) to be an economic downturn quarter with respect to a State then, as soon as practicable after such determination, the Secretary shall increase the allotment for the State and the fiscal year in

which such fiscal quarter occurs in accordance with subparagraph (B).

"(B) AMOUNT OF INCREASE.—

"(i) IN GENERAL.—The amount of an increase to the allotment of a State described in subparagraph (A) for a fiscal year shall be equal to the amount by which Federal payments made to the State for the preceding fiscal year under this title would have been increased (without regard to whether such payments would exceed the amount of the State's allotment for such preceding fiscal year) if the enhanced FMAP determined for the State for such preceding fiscal year had been increased to the same extent that the State's enhanced FMAP for the fiscal year involved is expected to be increased as a result of the application of section 1905(hh) relative to the enhanced FMAP that would apply to the State for the fiscal year involved without the application of such section.

"(ii) INCLUSION OF PROJECTED INCREASES.—In increasing the allotment of a State for a fiscal year under this para-

graph, the Secretary may base the calculation of such increase on projections made by the Secretary with respect to—

"(I) the number of fiscal quarters during such fiscal year that will be economic downturn quarters; and

"(II) the effect that the application of section 1905(hh) is expected to have on the enhanced FMAP of the State for such fiscal year.

"(C) DISREGARD OF INCREASED PAYMENTS FOR PURPOSES OF FUTURE ALLOTMENTS.—Any Federal payment made to a State under this title for a fiscal year in which the Federal medical assistance percentage for the State is determined under section 1905(hh) shall be disregarded when determining the allotment of the State for any subsequent year, including for purposes of applying this paragraph, to the extent that such payment exceeds the amount of the payment that would have been made to the State for the year if the Federal medical assistance percentage for the State and year had been determined without regard to such section.".

SEC. 205. STATE FLEXIBILITY TO USE ADMINISTRATIVE SIMPLIFICATION POLICIES FOR ENROLLMENT.

(a) PERMANENT EXTENSION OF MEDICAID AND CHIP EXPRESS LANE OPTION.—Section 1902(e)(13) of the Social Security Act (42 U.S.C. 1396a(e)(13)) is amended by striking subparagraph (I).

(b) EXTENDING EXPRESS LANE ELIGIBILITY TO ADULTS.—Section 1902(e)(13)(A) of the Social Security Act (42 U.S.C. 1396a(e)(13)(A)) is amended by adding at the end the following new clause:

"(iii) STATE OPTION TO EXTEND EXPRESS LANE ELIGIBILITY TO ADULTS.—

"(I) IN GENERAL.—At the option of the State, the State may apply the provisions of this paragraph with respect to determining eligibility under this title for an eligible individual (as defined in subclause (II)). In applying this paragraph in the case of a State making such an option, any reference in this paragraph to a child with respect to this title (other than a reference to child health assistance) shall be deemed to be a reference to an eligible individual.

"(II) ELIGIBLE INDIVIDUAL DEFINED.—In this clause, the term 'eligible individual' means—

"(aa) any individual (other than a child) whose income eligibility under the State plan or under a waiver of the plan for medical assistance is determined under paragraph (14); and

"(bb) an individual included in any other group of individuals the Secretary determines appropriate.".

(c) CONSENT BY BENEFIT UTILIZATION.—Section 1902(e)(13)(D)(i) of the Social Security Act (42 U.S.C. 1396a(e)(13)(D)(i)) is amended by inserting "by using medical assistance to access care," after "through electronic signature,".

(d) STUDY AND REPORT ON OPTIONS FOR AUTOMATIC ENROLLMENT IN MEDICAID AND CHIP.—

(1) STUDY.—The Secretary of Health and Human Services, by grant, contract, or interagency agency, shall conduct a study to identify options for, and barriers to, States automatically enrolling individuals who, on the basis of data and information

from income tax returns and other sources, are likely to be eligible for medical assistance under the State Medicaid plan established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or a waiver of such plan) or for child health assistance (or, if applicable, pregnancy-related assistance) under the State child health plan established under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) (or a waiver of such plan), and would not be required to pay a premium for enrollment in such a plan or waiver.

(2) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to Congress on the results of the study conducted under subsection (a). The report shall include the following:

(A) An analysis of the financial, regulatory, and legislative barriers that limit the ability of States to implement automatic enrollment for individuals described in subsection (a).

(B) An analysis of the extent to which State implementation of automatic enrollment for such individuals would reduce the number of uninsured individuals in each State.

(C) Recommendations for administrative and legislative actions that, if taken, would eliminate the barriers identified under subparagraph (A) and allow States to elect to automatically enroll individuals described in subsection (a) in the State Medicaid plan established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or a waiver of such plan) or for child health assistance (or, if applicable, pregnancy-related assistance) under the State child health plan established under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) (or a waiver of such plan).

TITLE III—ESTABLISHMENT OF A PUBLIC HEALTH CARE OPTION

SEC. 301. ESTABLISHMENT OF HEALTH PLAN.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this title as the "Secretary") shall establish a coordinated and low-cost health plan (referred to in this section as the "health plan") to provide access to quality health care for enrollees.

(b) INDIVIDUAL MARKET AVAILABILITY.—The Secretary shall make the health plan available in the individual market for plan year 2022 and each subsequent plan year.

(c) RULEMAKING.—The Secretary may promulgate such regulations as may be necessary to carry out this title.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this title.

SEC. 302. AVAILABILITY OF PLAN.

(a) ELIGIBILITY.—An individual shall be eligible to enroll in the health plan if such individual, for the entire period for which enrollment is sought—

(1) is a qualified individual within the meaning of section 1312 of the Patient Protection and Affordable Care Act (42 U.S.C. 18032);

(2) is not eligible for benefits under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.); and

(3) is not otherwise eligible for, or has been otherwise offered, employer-sponsored health care coverage.

(b) EXCHANGES.—The health plan shall be made available through the Exchanges, including the Small Business Health Options Program Exchange.

SEC. 303. AFFORDABILITY.

The Secretary shall ensure that coverage options for the health plan are not more costly than comparable options offered on the Exchange in the applicable market.

SEC. 304. PARTICIPATING PROVIDERS.

(a) REQUIREMENT TO PARTICIPATE IN ORDER TO BE ENROLLED UNDER MEDICARE.—Beginning January 1, 2022, the Secretary may require a health care provider enrolled under the Medicare program under section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) to be a participating provider under the health plan.

(b) REQUIREMENT TO PARTICIPATE IN ORDER TO PARTICIPATE IN MEDICAID.—Beginning January 1, 2022, the Secretary may require a health care provider under a State Medicaid plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) to also be a participating provider under the health plan.

SEC. 305. PROVIDER PAYMENT RATES.

The Secretary shall set competitive provider payment rates under the health plan using the best information publicly available and data otherwise accessible to the Secretary. The Secretary shall give consideration to existing provider payment rates for commercial health plans and provider costs to deliver care, giving special consideration to increased costs for providers to deliver care in rural and medically underserved areas.

SEC. 306. NO EFFECT ON MEDICARE BENEFITS OR MEDICARE TRUST FUNDS.

Nothing in this title shall—

(1) affect the benefits available under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.); or

(2) impact the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) or the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) (including the Medicare Prescription Drug Account within such Trust Fund).

TITLE IV—FAIR MEDICARE PAYMENTS TO RURAL PROVIDERS

SEC. 401. ENSURING FAIRNESS IN MEDICARE HOSPITAL PAYMENTS.

(a) HOSPITAL INPATIENT SERVICES.—

(1) IN GENERAL.—Section 1886(d)(3)(E) of the Social Security Act (42 U.S.C. 1395www(d)(3)(E)) is amended—

(A) in clause (i), in the first sentence, by striking "or (iii)" and inserting ", (iii), or (iv)"; and

(B) by adding at the end the following new clause:

"(iv) AREA WAGE INDEX FLOOR.—

"(I) IN GENERAL.—For discharges occurring on or after October 1, 2021, the area wage index applicable under this subparagraph to any hospital which is not located in a frontier State (as defined in clause (iii)(II)) may not be less than 0.85.

"(II) WAIVING BUDGET NEUTRALITY.—Pursuant to the fifth sentence of clause (i), this clause shall not be applied in a budget neutral manner.".

(2) WAIVING BUDGET NEUTRALITY.—

(A) TECHNICAL AMENDATORY CORRECTION.—Section 10324(a)(2) of Public Law 111–148 is amended by striking "third sentence" and inserting "fifth sentence".

(B) WAIVER.—Section 1886(d)(3)(E)(i) of the Social Security Act (42 U.S.C. 1395ww(d)(3)(E)(i)) is amended, in the fifth sentence—

(i) by striking "and the amendments" and inserting ", the amendments"; and

(ii) by inserting ", and the amendments made by section 401(a)(1) of the Health Care Improvement Act of 2021" after "Care Act".

(b) HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), is amended—

(1) in paragraph (2)(D), by striking "(19), the Secretary" and inserting "(19) and paragraph (23), the Secretary"; and

(2) by adding at the end the following new paragraph:

"(23) FLOOR ON AREA WAGE ADJUSTMENT FACTOR FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—With respect to covered OPD services furnished on or after January 1, 2022, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is not located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) may not be less than 0.85. The preceding sentence shall not be implemented in a budget neutral manner.".

TITLE V—COMMONSENSE COMPETITION AND ACCESS TO HEALTH INSURANCE

SEC. 501. PROVIDING SMALL BUSINESS HEALTH INSURANCE ACROSS STATE LINES.

Section 1333(a)(1)(A) of the Patient Protection and Affordable Care Act (42 U.S.C. 18053(a)(1)(A)) is amended by inserting "and small group markets" after "individual markets".

SEC. 502. REPORT AND MODELS.

Section 1333 of the Patient Protection and Affordable Care Act (42 U.S.C. 18053) is amended by adding at the end the following:

"(b) NAIC REPORT AND MODELS.—

"(1) IN GENERAL.—The Secretary shall request that the National Association of Insurance Commissioners submit, not later than December 31, 2021, to the Secretary a report concerning health plans provided for under this section. Such report shall include—

"(A) a description of the challenges that States would face by permitting issuers of qualified health plans to offer such plans in States other than those States where such plan was originally written or issued;

"(B) an assessment of how an out-of-State insurer would go about building an adequate provider network;

"(C) a description of how such challenges could be lessened without weakening the enforcement of laws and regulations described in subsection (a)(1)(B)(i) in any State that is included in a compact under this section;

"(D) a description of the commonalities that exist in State laws and opportunities to allow issuers of qualified health plans to offer such plans in States other than those States where such plan was originally written or issued; and

"(E) models to be used by States to establish and enter into interstate health care choice compacts under this section, which—

"(i) may include model legislation for use by States to enact laws to enter into such compacts;

"(ii) shall identify how States would continue to enforce, and not weaken, the laws and regulations described in subsection (a)(1)(B)(i) in any State that is included in such compact; and

"(iii) shall identify how such models would ensure that there is no violation of the conditions for Secretarial approval under subsection (a)(3).

"(2) OTHER ORGANIZATIONS AND ENTITIES.—In making the request under paragraph (1), the Secretary may also request that the National Association of Insurance Commissioners gather concepts for inclusion in the report under such paragraph from organizations and entities that have experience in offering qualified health plans in States in which such plans were not originally issued.".

TITLE VI—EMPOWERING MEDICARE SENIORS TO NEGOTIATE PRESCRIPTION DRUG PRICES

SEC. 601. AUTHORITY TO NEGOTIATE FAIR PRICES FOR MEDICARE PRESCRIPTION DRUGS.

(a) IN GENERAL.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended by striking subsection (i).

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the date of the enactment of this Act.

TITLE VII—COMMONSENSE REPORTING FOR EMPLOYERS

SEC. 701. VOLUNTARY PROSPECTIVE REPORTING SYSTEM.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, the Secretary of Labor, and the Administrator of the Small Business Administration, shall develop and implement guidance providing for a prospective reporting system meeting the requirements of subsection (b). Such system shall be available for use by employers on a voluntary basis beginning not later than January 1, 2023.

(b) REQUIREMENTS.—The system created under subsection (a) shall include—

(1) voluntary reporting by each participating employer that offers minimum essential coverage to its full-time employees and their dependents under an eligible employer-sponsored plan, not later than 45 days before the first day of the annual open enrollment period under section 1311(c)(6)(B) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(c)(6)(B)) for each calendar year, of—

(A) the name and employer identification number for purposes of section 6056 of the Internal Revenue Code of 1986 of the employer;

(B) a certification of—

(i) whether coverage meeting the definition of minimum essential coverage in section 5000A(f) of the Internal Revenue Code of 1986 is offered to the full-time employees (within the meaning of section 4980H of such Code) of the employer;

(ii) whether such coverage is offered to part-time employees of the employer;

(iii) whether such coverage is offered to dependents of employees;

(iv) whether such coverage is offered to spouses of employees;

(v) whether such coverage meets the minimum value requirement of section 36B(c)(2)(C)(ii) of such Code;

(vi) whether such coverage satisfies the requirements to qualify for one of the affordability safe harbors promulgated by the Secretary of the Treasury for purposes of section 4980H of such Code; and

(vii) whether the employer reasonably expects to be liable for any shared responsibility payment under section 4980H of such Code for such year;

(C) the months during the prospective reporting period that such coverage is available to individuals described in clauses (i) through (iv) of subparagraph (B);

(D) what waiting periods, if any, apply with respect to such coverage; and

(E) a list of all employer identification numbers of the employer for entities that employ employees within the employers control group under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code for 1986;

(2) processes necessary to ensure that Exchanges, the Federal Marketplace Data Services Hub, and the Internal Revenue Service can securely and confidentially access the information described in paragraph (1) as necessary to carry out their respective missions, and to provide to the Secretary of Health and Human Services additional information relating to eligibility determinations for advance payment of the premium tax credits under section 36B

of such Code and the cost-sharing subsidies under section 1402 of the Patient Protection and Affordable Care Act (42 U.S.C. 18071);

(3) a process to allow Exchanges to follow up with employers in order to obtain additional reasonably necessary information relating to an employee's eligibility for such advance payment or such cost-sharing subsidies, and to allow an employee to receive notification of any problem in verifying such eligibility; and

(4) a process to allow employers using the system to provide timely updates to the Federal Marketplace Data Services Hub regarding any cancellation of coverage or significant change in coverage for participating employees that would change the information reported under paragraph (1).

(c) EMPLOYER NOTIFICATION OF EMPLOYEE ENROLLMENT IN EXCHANGE PLANS.—Subparagraph (J) of section 1311(d)(4) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(d)(4)(J)) is amended by striking "to each employer" and all that follows through "(and the effective date of such cessation); and" and inserting "to each employer—

"(i) the name of each employee of the employer who enrolls in a qualified health

plan for a plan year, or whose dependents enroll in such a plan, at the time of such enrollment; or

"(ii) the name of each employee of the employer described in subparagraph (I)(ii) who ceases coverage under a qualified health plan during a plan year (and the effective date of such cessation); and".

(d) EXEMPTION FROM REPORTING REQUIREMENT UNDER INTERNAL REVENUE CODE OF 1986.—Section 6056 of the Internal Revenue Code of 1986 is amended by redesignating subsection (f) as subsection (g) and by inserting after subsection (e) the following new subsection:

"(f) EXEMPTION.—If, through the system created pursuant to section 701(a) of the Health Care Improvement Act of 2021, an employer provides prospective reporting for any calendar year that meets the requirements of section 701(b)(1) of such Act—

"(1) such employer shall be treated as satisfying the return requirements of subsections (a) and (b) for such year; and

"(2) such employer shall be treated as satisfying the requirements of subsection (c) for such year if the employer—

"(A) furnishes the statement described in such section to those employees of the employer whose names have been provided to the employer by an Exchange under section 1311(d)(4)(J)(i) of the Patient Protection and Affordable Care Act regarding enrollment of the employee or a dependent in a qualified health plan (as defined in section 1301 of such Act) through the Exchange; and

"(B) furnishes a copy of such statement with respect to such employees to the Secretary.".

(e) THIRD-PARTY FILING.—An employer may contract with a third party to make the report under subsection (b)(1) without affecting the employer's treatment as having satisfied the return requirements of subsections (a) and (b) of section 6056 of the Internal Revenue Code of 1986.

(f) ACCESS TO THE NATIONAL DIRECTORY OF NEW HIRES.—Subsection (i)(3) of section 453 of the Social Security Act (42 U.S.C. 653) is amended by adding at the end the following new sentence: "The Secretary of the Treasury and the Secretary of Health and Human Services shall have access to the information in the National Directory of New Hires for purposes of administering sec-

tion 36B and 4980H of the Internal Revenue Code of 1986 and section 1402 of the Patient Protection and Affordable Care Act (42 U.S.C. 18071). Subsection (k)(3) shall not apply to information received for purposes of the administration of such sections 36B and 4980H of such Code and section 1402 of such Act.".

(g) IMPROVING EMPLOYEE ACCESS TO ACCURATE EINS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of the Treasury shall develop and implement guidance for allowing any employee of an employer to receive, on request, the employer's employer identification number for purposes of section 6056 of the Internal Revenue Code of 1986. Employers shall provide the employer's employer identification number for purposes of section 6056 of the Internal Revenue Code of 1986 on one of the following documents of the employer's election:

(1) Health Insurance Marketplace Coverage Options Notice required under section 18B of the Fair Labor Standards Act of 1938 (29 U.S.C. 218b).

(2) Summary of Benefits and Coverage described in section 2715 of the Public Health Service Act (42 U.S.C. 300gg–15).

(3) Marketplace Employer Coverage tool.

(4) Annual benefits enrollment materials distributed to employees, including through an intranet or an online portal accessible by employees.

(5) Employee pay statements or Form W–2.

(h) FUNDING FOR VOLUNTARY PROSPECTIVE REPORTING SYSTEM.—It is the sense of Congress that building and maintaining the voluntary prospective reporting system described in this section will require appropriations to the Secretary of the Treasury, the Secretary of Health and Human Services, the Secretary of Labor, and the Administrator of the Small Business Administration, and that necessary sums to carry out the requirements of this section should be appropriated for such purpose.

SEC. 702. PROTECTION OF DEPENDENT PRIVACY.

(a) IN GENERAL.—Paragraph (1) of section 6055(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following flush sentence:

"For purposes of subparagraph (B)(i), in the case of an individual other than the primary insured, if the health insurance issuer or the employer is unable to collect or maintain information on the TINs of such individuals (other than for purposes of this section), the Secretary may allow the individual's full name and date of birth to be substituted for the name and TIN. In the event the Secretary allows the use of the individual's full name and

date of birth in lieu of the TIN, the Social Security Administration shall assist the Internal Revenue Service in providing data matches to determine the TIN associated with the name and date of birth provided by the Internal Revenue Service with respect to such individual.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to returns the due date for which is after the date that is 60 days after the date of the enactment of this Act.

SEC. 703. ELECTRONIC STATEMENTS.

(a) IN GENERAL.—Subsection (c) of section 6056 of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

"(3) ELECTRONIC DELIVERY.—An individual shall be deemed to have consented to receive the statement under this subsection in electronic form if such individual has affirmatively consented at any prior time, to the person who is the employer of the individual during the calendar year to which the statement relates, to receive such statement in electronic form. The preceding sentence shall not apply if the individual revokes consent in writing with respect to the statement under this subsection.".

(b) STATEMENTS RELATING TO HEALTH INSURANCE COVERAGE.—Subsection (c) of section 6055 of the Inter-

nal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

"(3) ELECTRONIC DELIVERY.—An individual shall be deemed to have consented to receive the statement under this subsection in electronic form if such individual has affirmatively consented at any prior time, to the person required to make such statement (such as the provider of the individual's health coverage), to receive in electronic form any private health information (such as electronic health records), unless the individual revokes such consent in writing.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to statements the due date for which is after December 31, 2021.

SEC. 704. GAO STUDIES.

(a) STUDY OF PAST EMPLOYER REPORTING.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study that evaluates, with respect to the period beginning on January 1, 2017, and ending on December 31, 2020—

(A) the notification of employers by Exchanges established under title I of the Patient Protection and Affordable Care Act (Public Law 111–148) that a full-time employee of the

employer has been determined eligible for advance payment of premium tax credits under section 36B of the Internal Revenue Code of 1986 or cost-sharing subsidies under section 1402 of such Act (42 U.S.C. 18071), including information regarding—

(i) the data elements included in the employer notification;

(ii) the process by which the notification forms were developed and sent to employers, including whether the process provided for a formal notice and comment period;

(iii) whether employers report that such notifications provided sufficient and relevant information for them to make appropriate decisions about whether to utilize the appeals process;

(iv) the total number of notifications sent to employers and the timeline of when such notifications were sent;

(v) differences in the notification process between the marketplace facilitated by the Federal Government and the State-Based Marketplaces; and

(vi) challenges that have arisen in the notification process, and recommendations to address these challenges; and

(B) the extent to which the Secretary of Health and Human Services has established a separate appeals process for employers who received such a notification to challenge the eligibility determination, as required by section 1411(f)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 18081(f)(2)).

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to the Committees on Finance and Health, Education, Labor, and Pensions of the Senate and the Committees on Ways and Means, Energy and Commerce, and Education and Labor of the House of Representatives a report on the results of the study conducted under paragraph (1).

(b) STUDY OF PROSPECTIVE REPORTING SYSTEM.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study that evaluates, with respect to the period beginning on January 1, 2023, and ending on December 31, 2023, the functionality of the prospective reporting system established pursuant to section 701, including the ac-

curacy of information collected, the number of employers electing to report under such system, and any challenges that have arisen in implementing such system.

(2) REPORT.—Not later than July 1, 2024, the Comptroller General shall submit to the Committees on Finance and Health, Education, Labor, and Pensions of the Senate and the Committees on Ways and Means, Energy and Commerce, and Education and Labor of the House of Representatives a report on the results of the study conducted under paragraph (1).

SEC. 705. TAX COMPLIANCE.

(a) IN GENERAL.—Section 6724(d)(1)(B)(xxv) of the Internal Revenue Code of 1986 is amended by inserting "or, in the case of an employer to which section 6056(f) applies, section 701(b)(1) of the Health Care Improvement Act of 2021" before ", or".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to returns required to be filed after the date of the enactment of this Act.

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U.S. GOVERNMENT INFORMATION GPO

II

117TH CONGRESS
1ST SESSION

S. 942

To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect.

IN THE SENATE OF THE UNITED STATES

MARCH 24, 2021

Ms. BALDWIN (for herself, Ms. STABENOW, Mr. CASEY, Mr. MERKLEY, Mr. BROWN, Mr. WARNER, Mr. MURPHY, Mr. BLUMENTHAL, Mr. MENENDEZ, Ms. ROSEN, Mr. KAINE, Mrs. MURRAY, Mrs. SHAHEEN, Ms. SMITH, Mr. VAN HOLLEN, Mr. KING, Mr. BENNET, Ms. KLOBUCHAR, Mr. REED, Ms. DUCKWORTH, Mr. CARPER, Mr. WYDEN, Mr. DURBIN, Mr. LEAHY, Mr. BOOKER, Ms. CORTEZ MASTO, Ms. WARREN, Mrs. FEINSTEIN, Mr. TESTER, and Mr. PETERS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "No Junk Plans Act".

SEC. 2. SHORT-TERM LIMITED DURATION INSURANCE RULE PROHIBITION.

The Secretary of Health and Human Services, the Secretary of the Treasury, and the Secretary of Labor may not take any action to implement, enforce, or otherwise give effect to the rule entitled "Short-Term, Limited Duration Insurance" (83 Fed. Reg. 38212 (August 3, 2018)), and the Secretaries may not promulgate any substantially similar rule.

○

Grp. Ex. 4
(Part 2 of 2)

II

Calendar No. 523

116TH CONGRESS
2D SESSION

H. R. 1425

IN THE SENATE OF THE UNITED STATES

JUNE 30, 2020
Received

AUGUST 13, 2020
Read the first time

SEPTEMBER 8, 2020
Read the second time and placed on the calendar

AN ACT

To amend the Patient Protection and Affordable Care Act to provide for a Improve Health Insurance Affordability Fund to provide for certain reinsurance payments to lower premiums in the individual health insurance market.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Patient Protection and Affordable Care Enhancement Act".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—LOWERING HEALTH CARE COSTS AND PROTECTING PEOPLE WITH PREEXISTING CONDITIONS

Sec. 101. Improving affordability by expanding premium assistance for consumers.
Sec. 102. Improving affordability by reducing out-of-pocket and premium costs for consumers.
Sec. 103. Expanding affordability for working families to fix the family glitch.
Sec. 104. Tax credit reconciliation protections for individuals receiving social security lump-sum payments.
Sec. 105. Preserving State option to implement health care Marketplaces.
Sec. 106. Establishing a Health Insurance Affordability Fund.
Sec. 107. Rescinding the short-term limited duration insurance regulation.
Sec. 108. Revoking section 1332 guidance.
Sec. 109. Requiring Marketplace outreach, educational activities, and annual enrollment targets.
Sec. 110. Report on effects of website maintenance during open enrollment.
Sec. 111. Promoting consumer outreach and education.
Sec. 112. Improving transparency and accountability in the Marketplace.
Sec. 113. Improving awareness of health coverage options.
Sec. 114. Promoting State innovations to expand coverage.
Sec. 115. Strengthening network adequacy.
Sec. 116. Protecting consumers from unreasonable rate hikes.
Sec. 117. Eligibility of DACA recipients for qualified health plans offered through Exchanges.

TITLE II—ENCOURAGING MEDICAID EXPANSION AND STRENGTHENING THE MEDICAID PROGRAM

Sec. 201. Incentivizing Medicaid expansion.
Sec. 202. Providing 12-months of continuous eligibility for Medicaid and CHIP.
Sec. 203. Mandatory 12-months of postpartum Medicaid eligibility.
Sec. 204. Reducing the administrative FMAP for nonexpansion States.
Sec. 205. Enhanced reporting requirements for nonexpansion states.
Sec. 206. Primary care pay increase.
Sec. 207. Permanent funding for CHIP.
Sec. 208. Permanent extension of CHIP enrollment and quality measures.
Sec. 209. State option to increase children's eligibility for Medicaid and CHIP.
Sec. 210. Medicaid coverage for citizens of Freely Associated States.
Sec. 211. Extension of full Federal medical assistance percentage to Indian health care providers.

TITLE III—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

Sec. 301. Establishing a Fair Drug Pricing Program.
Sec. 302. Drug manufacturer excise tax for noncompliance.
Sec. 303. Fair Price Negotiation Implementation Fund.

TITLE IV—PUBLIC HEALTH INVESTMENTS

Sec. 401. Supporting increased innovation.

TITLE I—LOWERING HEALTH CARE COSTS AND PROTECTING PEOPLE WITH PRE-EXISTING CONDITIONS

SEC. 101. IMPROVING AFFORDABILITY BY EXPANDING PREMIUM ASSISTANCE FOR CONSUMERS.

(a) IN GENERAL.—Section 36B(b)(3)(A) of the Internal Revenue Code of 1986 is amended to read as follows:

"(A) APPLICABLE PERCENTAGE.—The applicable percentage for any taxable year shall be the percentage such that the applicable percentage for any taxpayer whose household income is within an income tier specified in the following table shall increase, on a sliding scale in a linear manner, from the initial premium percentage to the final premium percentage specified in such table for such income tier:

"In the case of household income (expressed as a percent of poverty line) within the following income tier:	The initial premium percentage is—	The final premium percentage is—
Up to 150.0 percent	0.0	0.0
150.0 percent up to 200.0 percent	0.0	3.0
200.0 percent up to 250.0 percent	3.0	4.0
250.0 percent up to 300.0 percent	4.0	6.0
300.0 percent up to 400.0 percent	6.0	8.5
400.0 percent and higher	8.5	8.5".

(b) CONFORMING AMENDMENT.—Section 36B(c)(1)(A) of the Internal Revenue Code of 1986 is amended by striking "but does not exceed 400 percent".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2019.

SEC. 102. IMPROVING AFFORDABILITY BY REDUCING OUT-OF-POCKET AND PREMIUM COSTS FOR CONSUMERS.

Section 1302(c)(4) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(c)(4)) is amended by striking "calendar year)" and inserting "calendar year, based on estimates and projections for the applicable calendar year of the percentage (if any) by which the average per enrollee premium for eligible employer-sponsored health plans (as defined in section 5000A(f)(2) of the Internal Revenue Code of 1986) exceeds such average per enrollee premium for the preceding calendar year, as published in the National Health Expenditure Accounts)".

SEC. 103. EXPANDING AFFORDABILITY FOR WORKING FAMILIES TO FIX THE FAMILY GLITCH.

(a) IN GENERAL.—Clause (i) of section 36B(c)(2)(C) of the Internal Revenue Code of 1986 is amended to read as follows:

"(i) COVERAGE MUST BE AFFORDABLE.—

"(I) EMPLOYEES.—An employee shall not be treated as eligible for minimum essential coverage if such coverage consists of an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) and the employee's required contribution (within the meaning of section 5000A(e)(1)(B)) with respect to the plan exceeds 9.5 percent of the employee's household income.

"(II) FAMILY MEMBERS.—An individual who is eligible to enroll in an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) by reason of a relationship the individual bears to the employee shall not be treated as eligible for minimum essential coverage by reason of such eligibility to enroll if the employee's required contribution (within the meaning of section 5000A(e)(1)(B), determined by substituting 'family' for

'self-only') with respect to the plan exceeds 9.5 percent of the employee's household income.".

(b) CONFORMING AMENDMENTS.—

(1) Clause (ii) of section 36B(c)(2)(C) of the Internal Revenue Code of 1986 is amended by striking "Except as provided in clause (iii), an employee" and inserting "An individual".

(2) Clause (iii) of section 36B(c)(2)(C) of such Code is amended by striking "the last sentence of clause (i)" and inserting "clause (i)(II)".

(3) Clause (iv) of section 36B(c)(2)(C) of such Code is amended by striking "the 9.5 percent under clause (i)(II)" and inserting "the 9.5 percent under clauses (i)(I) and (i)(II)".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2021.

SEC. 104. TAX CREDIT RECONCILIATION PROTECTIONS FOR INDIVIDUALS RECEIVING SOCIAL SECURITY LUMP-SUM PAYMENTS.

(a) IN GENERAL.—Section 36B(d)(2) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

"(C) EXCLUSION OF PORTION OF LUMP-SUM SOCIAL SECURITY BENEFITS.—

"(i) IN GENERAL.—The term 'modified adjusted gross income' shall not include so much of any lump-sum social security benefit payment as is attributable to months ending before the beginning of the taxable year.

"(ii) LUMP-SUM SOCIAL SECURITY BENEFIT PAYMENT.—For purposes of this subparagraph, the term 'lump-sum social security benefit payment' means any payment of social security benefits (as defined in section 86(d)(1)) which constitutes more than 1 month of such benefits.

"(iii) ELECTION TO INCLUDE EXCLUDABLE AMOUNT.—A taxpayer may elect (at such time and in such manner as the Secretary may provide) to have this subparagraph not apply for any taxable year.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2019.

SEC. 105. PRESERVING STATE OPTION TO IMPLEMENT HEALTH CARE MARKETPLACES.

(a) IN GENERAL.—Section 1311 of the Patient Protection and Affordable Care Act (42 U.S.C. 18031) is amended—

(1) in subsection (a)—

(A) in paragraph (4)(B), by striking "under this subsection" and inserting "under this paragraph or paragraph (1)"; and

(B) by adding at the end the following new paragraph:

"(6) ADDITIONAL PLANNING AND ESTABLISHMENT GRANTS.—

"(A) IN GENERAL.—There shall be appropriated to the Secretary, out of any moneys in the Treasury not otherwise appropriated, $200 million to award grants to eligible States for the uses described in paragraph (3).

"(B) DURATION AND RENEWABILITY.—A grant awarded under subparagraph (A) shall be for a period of 2 years and may not be renewed.

"(C) LIMITATION.—A grant may not be awarded under subparagraph (A) after December 31, 2023.

"(D) ELIGIBLE STATE DEFINED.—For purposes of this paragraph, the term 'eligible

State' means a State that, as of the date of the enactment of this paragraph, is not operating an Exchange (other than an Exchange described in section 155.200(f) of title 45, Code of Federal Regulations)."; and

(2) in subsection (d)(5)(A)—

(A) by striking "OPERATIONS.—In establishing an Exchange under this section" and inserting "OPERATIONS.—

"(i) IN GENERAL.—In establishing an Exchange under this section (other than in establishing an Exchange pursuant to a grant awarded under subsection (a)(6))"; and

(B) by adding at the end the following:

"(ii) ADDITIONAL PLANNING AND ESTABLISHMENT GRANTS.—In establishing an Exchange pursuant to a grant awarded under subsection (a)(6), the State shall ensure that such Exchange is self-sustaining beginning on January 1, 2025, including allowing the Exchange to charge assessments or user fees to participating health insurance issuers, or to otherwise generate funding, to support its operations.".

(b) CLARIFICATION REGARDING FAILURE TO ESTABLISH EXCHANGE OR IMPLEMENT REQUIREMENTS.—Section 1321(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)) is amended—

(1) in paragraph (1), by striking "If" and inserting "Subject to paragraph (3), if"; and

(2) by adding at the end the following new paragraph:

"(3) CLARIFICATION.—This subsection shall not apply in the case of a State that elects to apply the requirements described in subsection (a) and satisfies the requirement described in subsection (b) on or after January 1, 2014.".

SEC. 106. ESTABLISHING A HEALTH INSURANCE AFFORDABILITY FUND.

Subtitle D of title I of the Patient Protection and Affordable Care Act is amended by inserting after part 5 (42 U.S.C. 18061 et seq.) the following new part:

"PART 6—IMPROVE HEALTH INSURANCE AFFORDABILITY FUND

"SEC. 1351. ESTABLISHMENT OF PROGRAM.

"There is hereby established the 'Improve Health Insurance Affordability Fund' to be administered by the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid

Services (in this section referred to as the 'Administrator'), to provide funding, in accordance with this part, to the 50 States and the District of Columbia (each referred to in this section as a 'State') beginning on January 1, 2022, for the purposes described in section 1352.

"SEC. 1352. USE OF FUNDS.

"(a) IN GENERAL.—A State shall use the funds allocated to the State under this part for one of the following purposes:

"(1) To provide reinsurance payments to health insurance issuers with respect to individuals enrolled under individual health insurance coverage (other than through a plan described in subsection (b)) offered by such issuers.

"(2) To provide assistance (other than through payments described in paragraph (1)) to reduce out-of-pocket costs, such as copayments, coinsurance, premiums, and deductibles, of individuals enrolled under qualified health plans offered on the individual market through an Exchange.

"(b) EXCLUSION OF CERTAIN GRANDFATHERED AND TRANSITIONAL PLANS.—For purposes of subsection (a), a plan described in this subsection is the following:

"(1) A grandfathered health plan (as defined in section 1251).

"(2) A plan (commonly referred to as a 'transitional plan') continued under the letter issued by the Centers for Medicare & Medicaid Services on November 14, 2013, to the State Insurance Commissioners outlining a transitional policy for coverage in the individual and small group markets to which section 1251 does not apply, and under the extension of the transitional policy for such coverage set forth in the Insurance Standards Bulletin Series guidance issued by the Centers for Medicare & Medicaid Services on March 5, 2014, February 29, 2016, February 13, 2017, April 9, 2018, March 25, 2019, and January 31, 2020, or under any subsequent extensions thereof.

"(3) Student health insurance coverage (as defined in section 147.145 of title 45, Code of Federal Regulations).

"SEC. 1353. STATE ELIGIBILITY AND APPROVAL; DEFAULT SAFEGUARD.

"(a) ENCOURAGING STATE OPTIONS FOR ALLOCATIONS.—

"(1) IN GENERAL.—To be eligible for an allocation of funds under this part for a year (beginning with 2022), a State shall submit to the Administrator an application at such time (but, in the case

of allocations for 2022, not later than 90 days after the date of the enactment of this part and, in the case of allocations for a subsequent year, not later than March 1 of the previous year) and in such form and manner as specified by the Administrator containing—

"(A) a description of how the funds will be used; and

"(B) such other information as the Administrator may require.

"(2) AUTOMATIC APPROVAL.—An application so submitted is approved unless the Administrator notifies the State submitting the application, not later than 60 days after the date of the submission of such application, that the application has been denied for not being in compliance with any requirement of this part and of the reason for such denial.

"(3) 5-YEAR APPLICATION APPROVAL.—If an application of a State is approved for a purpose described in section 1352 for a year, such application shall be treated as approved for such purpose for each of the subsequent 4 years.

"(4) REVOCATION OF APPROVAL.—The approval of an application of a State, with respect to a purpose described in section 1352, may be revoked

if the State fails to use funds provided to the State under this section for such purpose or otherwise fails to comply with the requirements of this section.

"(b) DEFAULT FEDERAL SAFEGUARD.—

"(1) 2022.—For 2022, in the case of a State that does not submit an application under subsection (a) by the 90-day submission date applicable to such year under subsection (a)(1) and in the case of a State that does submit such an application by such date that is not approved, the Administrator, in consultation with the State insurance commissioner, shall, from the amount calculated under paragraph (4) for such year, carry out the purpose described in paragraph (3) in such State for such year.

"(2) 2023 AND SUBSEQUENT YEARS.—For 2023 or a subsequent year, in the case of a State that does not have in effect an approved application under this section for such year, the Administrator, in consultation with the State insurance commissioner, shall, from the amount calculated under paragraph (4) for such year, carry out the purpose described in paragraph (3) in such State for such year.

"(3) SPECIFIED USE.—The amount described in paragraph (4), with respect to 2022 or a subse-

quent year, shall be used to carry out the purpose described in section 1352(a)(1) in each State described in paragraph (1) or (2) for such year, as applicable, by providing reinsurance payments to health insurance issuers with respect to attachment range claims (as defined in section 1354(b)(2)), using the dollar amounts specified in subparagraph (B) of such section for such year) in an amount equal to, subject to paragraph (5), the percentage (specified for such year by the Secretary under such subparagraph) of the amount of such claims.

"(4) AMOUNT DESCRIBED.—The amount described in this paragraph, with respect to 2022 or a subsequent year, is the amount equal to the total sum of amounts that the Secretary would otherwise estimate under section 1354(b)(2)(A)(i) for such year for each State described in paragraph (1) or (2) for such year, as applicable, if each such State were not so described for such year.

"(5) ADJUSTMENT.—For purposes of this subsection, the Secretary may apply a percentage under paragraph (3) with respect to a year that is less than the percentage otherwise specified in section 1354(b)(2)(B) for such year, if the cost of paying the total eligible attachment range claims for States

described in this subsection for such year at such percentage otherwise specified would exceed the amount calculated under paragraph (4) for such year.

"SEC. 1354. ALLOCATIONS.

"(a) APPROPRIATION.—For the purpose of providing allocations for States under subsection (b) and payments under section 1353(b) there is appropriated, out of any money in the Treasury not otherwise appropriated, $10,000,000,000 for 2022 and each subsequent year.

"(b) ALLOCATIONS.—

"(1) PAYMENT.—

"(A) IN GENERAL.—From amounts appropriated under subsection (a) for a year, the Secretary shall, with respect to a State not described in section 1353(b) for such year and not later than the date specified under subparagraph (B) for such year, allocate for such State the amount determined for such State and year under paragraph (2).

"(B) SPECIFIED DATE.—For purposes of subparagraph (A), the date specified in this subparagraph is—

"(i) for 2022, the date that is 45 days after the date of the enactment of this part; and

"(ii) for 2023 or a subsequent year, January 1 of the respective year.

"(C) NOTIFICATIONS OF ALLOCATION AMOUNTS.—For 2023 and each subsequent year, the Secretary shall notify each State of the amount determined for such State under paragraph (2) for such year by not later than January 1 of the previous year.

"(2) ALLOCATION AMOUNT DETERMINATIONS.—

"(A) IN GENERAL.—For purposes of paragraph (1), the amount determined under this paragraph for a year for a State described in paragraph (1)(A) for such year is the amount equal to—

"(i) the amount that the Secretary estimates would be expended under this part for such year on attachment range claims of individuals residing in such State if such State used such funds only for the purpose described in paragraph (1) of section 1352(a) at the dollar amounts and per-

centage specified under subparagraph (B) for such year; minus

"(ii) the amount, if any, by which the Secretary determines—

"(I) the estimated amount of premium tax credits under section 36B of the Internal Revenue Code of 1986 that would be attributable to individuals residing in such State for such year without application of this part; exceeds

"(II) the estimated amount of premium tax credits under section 36B of the Internal Revenue Code of 1986 that would be attributable to individuals residing in such State for such year if such State were a State described in section 1353(b) for such year.

For purposes of the previous sentence and section 1353(b)(3), the term 'attachment range claims' means, with respect to an individual, the claims for such individual that exceed a dollar amount specified by the Secretary for a year, but do not exceed a ceiling dollar amount speci-

fied by the Secretary for such year, under subparagraph (B).

"(B) SPECIFICATIONS.—For purposes of subparagraph (A) and section 1353(b)(3), the Secretary shall determine the dollar amounts and the percentage to be specified under this subparagraph for a year in a manner to ensure that the total amount of expenditures under this part for such year is estimated to equal the total amount appropriated for such year under subsection (a) if such expenditures were used solely for the purpose described in paragraph (1) of section 1352(a) for attachment range claims at the dollar amounts and percentage so specified for such year.

"(3) AVAILABILITY.—Funds allocated to a State under this subsection for a year shall remain available through the end of the subsequent year.".

SEC. 107. RESCINDING THE SHORT-TERM LIMITED DURATION INSURANCE REGULATION.

(a) FINDINGS.—Congress finds the following:

(1) On August 3, 2018, the Administration issued a final rule entitled "Short-Term, Limited-Duration Insurance" (83 Fed. Reg. 38212).

(2) The final rule dramatically expands the sale and marketing of insurance that—

(A) may discriminate against individuals living with preexisting health conditions, including children with complex medical needs and disabilities and their families;

(B) lacks important financial protections provided by the Patient Protection and Affordable Care Act (Public Law 111–148), including the prohibition of annual and lifetime coverage limits and annual out-of-pocket limits, that may increase the cost of treatment and cause financial hardship to those requiring medical care, including children with complex medical needs and disabilities and their families; and

(C) excludes coverage of essential health benefits including hospitalization, prescription drugs, and other lifesaving care.

(3) The implementation and enforcement of the final rule weakens critical protections for up to 130 million Americans living with preexisting health conditions and may place a large financial burden on those who enroll in short-term limited-duration insurance, which jeopardizes Americans' access to quality, affordable health insurance.

(b) PROHIBITION.—The Secretary of Health and Human Services, the Secretary of the Treasury, and the Secretary of Labor—

(1) may not take any action to implement, enforce, or otherwise give effect to the rule entitled "Short-Term, Limited Duration Insurance" (83 Fed. Reg. 38212 (August 3, 2018));

(2) shall apply any regulation revised by such rule as if such rule had not been issued; and

(3) may not promulgate any substantially similar rule.

SEC. 108. REVOKING SECTION 1332 GUIDANCE.

(a) FINDINGS.—Congress finds the following:

(1) On October 24, 2018, the administration published new guidance to carry out section 1332 of the Patient Protection and Affordable Care Act (42 U.S.C. 18052) entitled "State Relief and Empowerment Waivers" (83 Fed. Reg. 53575).

(2) The new guidance encourages States to provide health insurance coverage through insurance plans that may discriminate against individuals with preexisting health conditions, including the one in four Americans living with a disability.

(3) The implementation and enforcement of the new guidance weakens protections for the millions of

Americans living with preexisting health conditions and jeopardizes Americans' access to quality, affordable health insurance coverage.

(b) PROVIDING THAT CERTAIN GUIDANCE RELATED TO WAIVERS FOR STATE INNOVATION UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT SHALL HAVE NO FORCE OR EFFECT.—Beginning July 1, 2020, the Secretary of Health and Human Services and the Secretary of the Treasury may not take any action to implement, enforce, or otherwise give effect to the guidance entitled "State Relief and Empowerment Waivers" (83 Fed. Reg. 53575 (October 24, 2018)), including any such action that would result in individuals losing health insurance coverage that includes the essential health benefits package (as defined in subsection (a) of section 1302 of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) without regard to any waiver of any provision of such package under a waiver under such section 1332), including the maternity and newborn care essential health benefit described in subsection (b)(1)(D) of such section, including any such action that would result in a decrease in the number of such individuals enrolled in coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) compared to

the number of such individuals who would have been so enrolled in such coverage had such action not been taken, including any such action that would, with respect to individuals with substance use disorders, including opioid use disorders, reduce the availability or affordability of coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) compared to the availability or affordability, respectively, of such coverage had such action not been taken, including any such action that would result, with respect to vulnerable populations (including low-income individuals, elderly individuals, and individuals with serious health issues or who have a greater risk of developing serious health issues), in a decrease in the availability of coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) with coverage and cost sharing protections required under section 1332(b)(1)(B) of such Act (42 U.S.C. 18052(b)(1)(B)), including any such action that would, with respect to individuals with preexisting conditions, reduce the affordability of coverage that is at least as comprehensive as the coverage defined in section 1302(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(a)) compared to the affordability of

such coverage had such action not been taken, including any such action that would result in higher health insurance premiums for individuals enrolled in health insurance coverage that is at least as comprehensive as the coverage defined in section 1302(b) of such Act (42 U.S.C. 18022(b)), and the Secretaries may not promulgate any substantially similar guidance or rule. Nothing in the previous sentence shall be construed to affect the approval of waivers under section 1332 of the Patient Protection and Affordable Care Act (42 U.S.C. 18052) that establish reinsurance programs that are consistent with the requirements under subsection (b)(1) of such section (42 U.S.C. 18052(b)(1)), lower health insurance premiums, and protect health insurance coverage for people with preexisting conditions.

(c) GAO REPORT ON AFFECT OF STATE INNOVATION WAIVERS ON COVERAGE OF INDIVIDUALS AND ON MENTAL HEALTH HEALTH CARE TREATMENT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the number of individuals expected to lose access to health insurance coverage (as defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91)) if subsection (b) were not enacted and waivers under section 1332 of the Patient Protection and

Affordable Care Act (42 U.S.C. 18052) were approved under the guidance described in such subsection (b). Such report shall include an analysis of the expected effect such waivers approved under such guidance would have on mental health care treatment.

SEC. 109. REQUIRING MARKETPLACE OUTREACH, EDUCATIONAL ACTIVITIES, AND ANNUAL ENROLLMENT TARGETS.

(a) IN GENERAL.—Section 1321(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)), as amended by section 105(b), is further amended by adding at the end the following new paragraphs:

"(4) OUTREACH AND EDUCATIONAL ACTIVITIES.—

"(A) IN GENERAL.—In the case of an Exchange established or operated by the Secretary within a State pursuant to this subsection, the Secretary shall carry out outreach and educational activities for purposes of informing individuals about qualified health plans offered through the Exchange, including by informing such individuals of the availability of coverage under such plans and financial assistance for coverage under such plans. Such outreach and educational activities shall be provided in a

manner that is culturally and linguistically appropriate to the needs of the populations being served by the Exchange (including hard-to-reach populations, such as racial and sexual minorities, limited English proficient populations, individuals in rural areas, veterans, and young adults) and shall be provided to populations residing in high health disparity areas (as defined in subparagraph (E)) served by the Exchange, in addition to other populations served by the Exchange.

"(B) LIMITATION ON USE OF FUNDS.—No funds appropriated under this paragraph shall be used for expenditures for promoting non-ACA compliant health insurance coverage.

"(C) NON-ACA COMPLIANT HEALTH INSURANCE COVERAGE.—For purposes of subparagraph (B):

"(i) The term 'non-ACA compliant health insurance coverage' means health insurance coverage, or a group health plan, that is not a qualified health plan.

"(ii) Such term includes the following:

"(I) An association health plan.

"(II) Short-term limited duration insurance.

"(D) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are hereby appropriated for fiscal year 2022 and each subsequent fiscal year, $100,000,000 to carry out this paragraph. Funds appropriated under this subparagraph shall remain available until expended.

"(E) HIGH HEALTH DISPARITY AREA DEFINED.—For purposes of subparagraph (A), the term 'high health disparity area' means a contiguous geographic area that—

"(i) is located in one census tract or ZIP code;

"(ii) has measurable and documented racial, ethnic, or geographic health disparities;

"(iii) has a low-income population, as demonstrated by—

"(I) average income below 138 percent of the Federal poverty line; or

"(II) a rate of participation in the special supplemental nutrition program under section 17 of the Child

Nutrition Act of 1966 (42 U.S.C. 1786) that is higher than the national average rate of participation in such program;

"(iv) has poor health outcomes, as demonstrated by—

"(I) lower life expectancy than the national average; or

"(II) a higher percentage of instances of low birth weight than the national average; and

"(v) is part of a Metropolitan Statistical Area identified by the Office of Management and Budget.

"(5) ANNUAL ENROLLMENT TARGETS.—For plan year 2021 and each subsequent plan year, in the case of an Exchange established or operated by the Secretary within a State pursuant to this subsection, the Secretary shall establish annual enrollment targets for such Exchange for such year.".

(b) STUDY AND REPORT.—Not later than 30 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall release to Congress all aggregated documents relating to studies and data sets that were created on or after January 1, 2014, and related

to marketing and outreach with respect to qualified health plans offered through Exchanges under title I of the Patient Protection and Affordable Care Act (42 U.S.C. 18001 et seq.).

SEC. 110. REPORT ON EFFECTS OF WEBSITE MAINTENANCE DURING OPEN ENROLLMENT.

Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report examining whether the Department of Health and Human Services has been conducting maintenance on the website commonly referred to as "Healthcare.gov" during annual open enrollment periods (as described in section 1311(c)(6)(B) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(c)(6)(B)) in such a manner so as to minimize any disruption to the use of such website resulting from such maintenance.

SEC. 111. PROMOTING CONSUMER OUTREACH AND EDUCATION.

(a) IN GENERAL.—Section 1311(i) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(i)) is amended—

(1) in paragraph (2), by adding at the end the following new subparagraph:

"(C) SELECTION OF RECIPIENTS.—In the case of an Exchange established and operated by the Secretary within a State pursuant to section 1321(c), in awarding grants under paragraph (1), the Exchange shall—

"(i) select entities to receive such grants based on an entity's demonstrated capacity to carry out each of the duties specified in paragraph (3);

"(ii) not take into account whether or not the entity has demonstrated how the entity will provide information to individuals relating to group health plans offered by a group or association of employers described in section 2510.3–5(b) of title 29, Code of Federal Regulations (or any successor regulation), or short-term limited duration insurance (as defined by the Secretary for purposes of section 2791(b)(5) of the Public Health Service Act); and

"(iii) ensure that, each year, the Exchange awards such a grant to—

"(I) at least one entity described in this paragraph that is a community

and consumer-focused nonprofit group; and

"(II) at least one entity described in subparagraph (B), which may include another community and consumer-focused nonprofit group in addition to any such group awarded a grant pursuant to subclause (I).

In awarding such grants, an Exchange may consider an entity's record with respect to waste, fraud, and abuse for purposes of maintaining the integrity of such Exchange.";

(2) in paragraph (3)—

(A) by amending subparagraph (C) to read as follows:

"(C) facilitate enrollment, including with respect to individuals with limited English proficiency and individuals with chronic illnesses, in qualified health plans, State medicaid plans under title XIX of the Social Security Act, and State child health plans under title XXI of such Act;";

(B) in subparagraph (D), by striking "and" at the end;

(C) in subparagraph (E), by striking the period at the end and inserting "; and";

(D) by inserting after subparagraph (E) the following new subparagraph:

"(F) provide referrals to community-based organizations that address social needs related to health outcomes."; and

(E) by adding at the end the following flush left sentence:

"The duties specified in the preceding sentence may be carried out by such a navigator at any time during a year.";

(3) in paragraph (4)(A)—

(A) in the matter preceding clause (i), by striking "not";

(B) in clause (i)—

(i) by inserting "not" before "be"; and

(ii) by striking "; or" and inserting a semicolon;

(C) in clause (ii)—

(i) by inserting "not" before "receive"; and

(ii) by striking the period and inserting a semicolon; and

(D) by adding at the end the following new clauses:

"(iii) maintain physical presence in the State of the Exchange so as to allow in-person assistance to consumers; and

"(iv) receive opioid specific education and training that ensures the navigator can best educate individuals on qualified health plans offered through an Exchange, specifically coverage under such plans for opioid health care treatment."; and

(4) in paragraph (6)—

(A) by striking "FUNDING.—Grants under" and inserting "FUNDING.—

"(A) STATE EXCHANGES.—Grants under"; and

(B) by adding at the end the following new subparagraph:

"(B) FEDERAL EXCHANGES.—For purposes of carrying out this subsection, with respect to an Exchange established and operated by the Secretary within a State pursuant to section 1321(c), the Secretary shall obligate $100,000,000 out of amounts collected through the user fees on participating health insurance

issuers pursuant to section 156.50 of title 45, Code of Federal Regulations (or any successor regulations), for fiscal year 2022 and each subsequent fiscal year. Such amount for a fiscal year shall remain available until expended.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2021.

SEC. 112. IMPROVING TRANSPARENCY AND ACCOUNTABILITY IN THE MARKETPLACE.

(a) OPEN ENROLLMENT REPORTS.—For plan year 2021 and each subsequent year, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in coordination with the Secretary of the Treasury and the Secretary of Labor, shall issue biweekly public reports during the annual open enrollment period on the performance of the federally facilitated Exchange operated pursuant to section 1321(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)). Each such report shall include a summary, including information on a State-by-State basis where available, of—

(1) the number of unique website visits;

(2) the number of individuals who create an account;

(3) the number of calls to the call center;

(4) the average wait time for callers contacting the call center;

(5) the number of individuals who enroll in a qualified health plan; and

(6) the percentage of individuals who enroll in a qualified health plan through each of—

(A) the website;

(B) the call center;

(C) navigators;

(D) agents and brokers;

(E) the enrollment assistant program;

(F) directly from issuers or web brokers; and

(G) other means.

(b) OPEN ENROLLMENT AFTER ACTION REPORT.—For plan year 2021 and each subsequent year, the Secretary, in coordination with the Secretary of the Treasury and the Secretary of Labor, shall publish an after action report not later than 3 months after the completion of the annual open enrollment period regarding the performance of the Exchange described in subsection (a) for the applicable plan year. Each such report shall include a summary, including information on a State-by-State basis where available, of—

(1) the open enrollment data reported under subsection (a) for the entirety of the enrollment period; and

(2) activities related to patient navigators described in section 1311(i) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(i)), including—

(A) the performance objectives established by the Secretary for such patient navigators;

(B) the number of consumers enrolled by such a patient navigator;

(C) an assessment of how such patient navigators have met established performance metrics, including a detailed list of all patient navigators, funding received by patient navigators, and whether established performance objectives of patient navigators were met; and

(D) with respect to the performance objectives described in subparagraph (A)—

(i) whether such objectives assess the full scope of patient navigator responsibilities, including general education, plan selection, and determination of eligibility for tax credits, cost-sharing reductions, or other coverage;

(ii) how the Secretary worked with patient navigators to establish such objectives; and

(iii) how the Secretary adjusted such objectives for case complexity and other contextual factors.

(c) REPORT ON ADVERTISING AND CONSUMER OUTREACH.—Not later than 3 months after the completion of the annual open enrollment period for plan year 2021, the Secretary shall issue a report on advertising and outreach to consumers for the open enrollment period for plan year 2021. Such report shall include a description of—

(1) the division of spending on individual advertising platforms, including television and radio advertisements and digital media, to raise consumer awareness of open enrollment;

(2) the division of spending on individual outreach platforms, including email and text messages, to raise consumer awareness of open enrollment; and

(3) whether the Secretary conducted targeted outreach to specific demographic groups and geographic areas.

(b) PROMOTING TRANSPARENCY AND ACCOUNTABILITY IN THE ADMINISTRATION'S EXPENDITURES OF EXCHANGE USER FEES.—For plan year 2021 and each

subsequent plan year, not later than the date that is 3 months after the end of such plan year, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress and make available to the public an annual report on the expenditures by the Department of Health and Human Services of user fees collected pursuant to section 156.50 of title 45, Code of Federal Regulations (or any successor regulations). Each such report for a plan year shall include a detailed accounting of the amount of such user fees collected during such plan year and of the amount of such expenditures used during such plan year for the federally facilitated Exchange operated pursuant to section 1321(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18041(c)) on outreach and enrollment activities, navigators, maintenance of Healthcare.gov, and operation of call centers.

SEC. 113. IMPROVING AWARENESS OF HEALTH COVERAGE OPTIONS.

(a) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Labor, in consultation with the Secretary of Health and Human Services, shall update, and make publicly available in a prominent location on the website of the Department of Labor, the model Consolidated Omnibus Budget Reconciliation Act of 1985 (referred to in this section as

"COBRA") continuation coverage general notice and the model COBRA continuation coverage election notice developed by the Secretary of Labor for purposes of facilitating compliance of group health plans with the notification requirements under section 606 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1166). In updating each such notice, the Secretary of Labor shall include information regarding any Exchange established under title I of the Patient Protection and Affordable Care Act (42 U.S.C. 18001 et seq.) through which a qualified beneficiary may be eligible to enroll in a qualified health plan, including—

(1) the publicly accessible Internet website address for such Exchange;

(2) the publicly accessible Internet website address for the Find Local Help directory maintained by the Department of Health and Human Services on the healthcare.gov Internet website (or a successor website);

(3) a clear explanation that—

(A) an individual who is eligible for continuation coverage may also be eligible to enroll, with financial assistance, in a qualified health plan offered through such Exchange, but, in the case that such individual elects to enroll in such

continuation coverage and subsequently elects to terminate such continuation coverage before the period of such continuation coverage expires, such individual will not be eligible to enroll in a qualified health plan offered through such Exchange during a special enrollment period; and

(B) an individual who elects to enroll in continuation coverage will remain eligible to enroll in a qualified health plan offered through such Exchange during an open enrollment period and may be eligible for financial assistance with respect to enrolling in such a qualified health plan;

(4) information on consumer protections with respect to enrolling in a qualified health plan offered through such Exchange, including the requirement for such a qualified health plan to provide coverage for essential health benefits (as defined in section 1302(b) of such Act (42 U.S.C. 18022(b)) and the requirements applicable to such a qualified health plan under part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.); and

(5) information on the availability of financial assistance with respect to enrolling in a qualified

health plan, including the maximum income limit for eligibility for a premium tax credit under section 36B of the Internal Revenue Code of 1986.

(b) NAME OF NOTICES.—In addition to updating the model COBRA continuation coverage general notice and the model COBRA continuation coverage election notice under paragraph (1), the Secretary of Labor shall rename each such notice as the "model COBRA continuation coverage and Affordable Care Act coverage general notice" and the "model COBRA continuation coverage and Affordable Care Act coverage election notice", respectively.

(c) CONSUMER TESTING.—Prior to making publicly available the model COBRA continuation coverage general notice and the model COBRA continuation coverage election notice updated under paragraph (1), the Secretary of Labor shall provide an opportunity for consumer testing of each such notice, as so updated, to ensure that each such notice is clear and understandable to the average participant or beneficiary of a group health plan.

(d) DEFINITIONS.—In this subsection:

(1) CONTINUATION COVERAGE.—The term "continuation coverage", with respect to a group health plan, has the meaning given such term in section 602 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1162).

(2) GROUP HEALTH PLAN.—The term "group health plan" has the meaning given such term in section 607 of such Act (29 U.S.C. 1167).

(3) QUALIFIED BENEFICIARY.—The term "qualified beneficiary" has the meaning given such term in such section 607.

(4) QUALIFIED HEALTH PLAN.—The term "qualified health plan" has the meaning given such term in section 1301 of the Patient Protection and Affordable Care Act (42 U.S.C. 18021).

SEC. 114. PROMOTING STATE INNOVATIONS TO EXPAND COVERAGE.

(a) IN GENERAL.—Subject to subsection (d), the Secretary of Health and Human Services shall award grants to eligible State agencies to enable such States to explore innovative solutions to promote greater enrollment in health insurance coverage in the individual and small group markets, including activities described in subsection (c).

(b) ELIGIBILITY.—For purposes of subsection (a), eligible State agencies are Exchanges established by a State under title I of the Patient Protection and Affordable Care Act (42 U.S.C. 18001 et seq.) and State agencies with primary responsibility over health and human services for the State involved.

(c) USE OF FUNDS.—For purposes of subsection (a), the activities described in this subsection are the following:

(1) State efforts to streamline health insurance enrollment procedures in order to reduce burdens on consumers and facilitate greater enrollment in health insurance coverage in the individual and small group markets, including automatic enrollment and re-enrollment of, or pre-populated applications for, individuals without health insurance who are eligible for tax credits under section 36B of the Internal Revenue Code of 1986, with the ability to opt out of such enrollment.

(2) State investment in technology to improve data sharing and collection for the purposes of facilitating greater enrollment in health insurance coverage in such markets.

(3) Implementation of a State version of an individual mandate to be enrolled in health insurance coverage.

(4) Feasibility studies to develop comprehensive and coherent State plan for increasing enrollment in the individual and small group market.

(d) FUNDING.—For purposes of carrying out this section, there is hereby appropriated, out of any funds in the Treasury not otherwise appropriated, $200,000,000

for each of the fiscal years 2022 through 2024. Such amount shall remain available until expended.

SEC. 115. STRENGTHENING NETWORK ADEQUACY.

(a) IN GENERAL.—Section 1311(d) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(d)) is amended by adding at the end the following new paragraph:

"(8) NETWORK ADEQUACY STANDARDS.—

"(A) CERTAIN EXCHANGES.—In the case of an Exchange operated by the Secretary pursuant section 1321(c)(1) or an Exchange described in section 155.200(f) of title 42, Code of Federal Regulations (or a successor regulation), the Exchange shall require each qualified health plan offered through such Exchange to meet such quantitative network adequacy standards as the Secretary may prescribe for purposes of this subparagraph.

"(B) STATE EXCHANGES.—In the case of an Exchange not described in subparagraph (A), the Exchange shall establish quantitative network adequacy standards with respect to qualified health plans offered through such Exchange and require such plans to meet such standards.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to plan years beginning on or after January 1, 2022.

SEC. 116. PROTECTING CONSUMERS FROM UNREASONABLE RATE HIKES.

(a) PROTECTION FROM EXCESSIVE, UNJUSTIFIED, OR UNFAIRLY DISCRIMINATORY RATES.—The first section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94), as added by section 1003 of the Patient Protection and Affordable Care Act (Public Law 111–148), is amended by adding at the end the following new subsection:

"(e) PROTECTION FROM EXCESSIVE, UNJUSTIFIED, OR UNFAIRLY DISCRIMINATORY RATES.—

"(1) AUTHORITY OF STATES.—Nothing in this section shall be construed to prohibit a State from imposing requirements (including requirements relating to rate review standards and procedures and information reporting) on health insurance issuers with respect to rates that are in addition to the requirements of this section and are more protective of consumers than such requirements.

"(2) CONSULTATION IN RATE REVIEW PROCESS.—In carrying out this section, the Secretary

shall consult with the National Association of Insurance Commissioners and consumer groups.

"(3) DETERMINATION OF WHO CONDUCTS REVIEWS FOR EACH STATE.—The Secretary shall determine, after the date of enactment of this section and periodically thereafter, the following:

"(A) In which markets in each State the State insurance commissioner or relevant State regulator shall undertake the corrective actions under paragraph (4), based on the Secretary's determination that the State regulator is adequately undertaking and utilizing such actions in that market.

"(B) In which markets in each State the Secretary shall undertake the corrective actions under paragraph (4), in cooperation with the relevant State insurance commissioner or State regulator, based on the Secretary's determination that the State is not adequately undertaking and utilizing such actions in that market.

"(4) CORRECTIVE ACTION FOR EXCESSIVE, UNJUSTIFIED, OR UNFAIRLY DISCRIMINATORY RATES.—In accordance with the process established under this section, the Secretary or the relevant

State insurance commissioner or State regulator shall take corrective actions to ensure that any excessive, unjustified, or unfairly discriminatory rates are corrected prior to implementation, or as soon as possible thereafter, through mechanisms such as—

"(A) denying rates;

"(B) modifying rates; or

"(C) requiring rebates to consumers.

"(5) NONCOMPLIANCE.—Failure to comply with any corrective action taken by the Secretary under this subsection may result in the application of civil monetary penalties under section 2723 and, if the Secretary determines appropriate, make the plan involved ineligible for classification as a qualified health plan.".

(b) CLARIFICATION OF REGULATORY AUTHORITY.—Such section is further amended—

(1) in subsection (a)—

(A) in the heading, by striking "PREMIUM" and inserting "RATE";

(B) in paragraph (1), by striking "unreasonable increases in premiums" and inserting "potentially excessive, unjustified, or unfairly discriminatory rates, including premiums,"; and

(C) in paragraph (2)—

(i) by striking "an unreasonable premium increase" and inserting "a potentially excessive, unjustified, or unfairly discriminatory rate";

(ii) by striking "the increase" and inserting "the rate"; and

(iii) by striking "such increases" and inserting "such rates"; and

(2) in subsection (b)—

(A) by striking "premium increases" each place it appears and inserting "rates"; and

(B) in paragraph (2)(B), by striking "premium" and inserting "rate".

(c) CONFORMING AMENDMENTS.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

(1) in section 2723 (42 U.S.C. 300gg–22), as redesignated by the Patient Protection and Affordable Care Act—

(A) in subsection (a)—

(i) in paragraph (1), by inserting "and section 2794" after "this part"; and

(ii) in paragraph (2), by inserting "or section 2794" after "this part"; and

(B) in subsection (b)—

(i) in paragraph (1), by inserting "and section 2794" after "this part"; and

(ii) in paragraph (2)—

(I) in subparagraph (A), by inserting "or section 2794 that is" after "this part"; and

(II) in subparagraph (C)(ii), by inserting "or section 2794" after "this part"; and

(2) in section 2761 (42 U.S.C. 300gg–61)—

(A) in subsection (a)—

(i) in paragraph (1), by inserting "and section 2794" after "this part"; and

(ii) in paragraph (2)—

(I) by inserting "or section 2794" after "set forth in this part"; and

(II) by inserting "and section 2794" after "the requirements of this part"; and

(B) in subsection (b)—

(i) by inserting "and section 2794" after "this part"; and

(ii) by inserting "and section 2794" after "part A".

(d) APPLICABILITY TO GRANDFATHERED PLANS.—Section 1251(a)(4)(A) of the Patient Protection and Affordable Care Act (Public Law 111–148), as added by section 2301 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152), is amended by adding at the end the following:

"(v) Section 2794 (relating to reasonableness of rates with respect to health insurance coverage).".

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this Act such sums as may be necessary.

(f) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of enactment of this Act and shall be implemented with respect to health plans beginning not later than January 1, 2022.

SEC. 117. ELIGIBILITY OF DACA RECIPIENTS FOR QUALIFIED HEALTH PLANS OFFERED THROUGH EXCHANGES.

(a) IN GENERAL.—Section 1312(f)(3) of the Patient Protection and Affordable Care Act (42 U.S.C. 18032(f)(3)) is amended—

(1) by striking "or an alien lawfully present in the United States" and inserting ", an alien lawfully

present in the United States, or a DACA recipient"; and

(2) by adding at the end the following: "For purposes of the previous sentence, the term 'DACA recipient' means an individual who was granted deferred action pursuant to the Deferred Action for Childhood Arrivals Program announced in the memorandum of the Secretary of Homeland Security dated June 15, 2012, and for whom such grant remains valid.".

(b) APPLICATION OF REDUCED COST-SHARING.—Section 1402(e)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 18071(e)(2)) is amended by adding at the end the following: "A DACA recipient (as defined in section 1312(f)(3)) shall be treated as lawfully present for purposes of this section.".

(c) ELIGIBILITY FOR ADVANCE PAYMENTS.—Section 1412(d) of the Patient Protection and Affordable Care Act (42 U.S.C. 18082(d)) is amended by adding at the end the following: "For purposes of the previous sentence, a DACA recipient (as defined in section 1312(f)(3)) shall be treated as lawfully present in the United States.".

(d) VERIFICATION OF ELIGIBILITY.—Section 1411(e)(2)(B) of the Patient Protection and Affordable Care Act (42 U.S.C. 18081(e)(2)(B)) is amended—

(1) in clause (i)(I), by inserting "or a DACA recipient (as defined in section 1312(f)(3))" after "an alien lawfully present in the United States"; and

(2) in clause (ii), by inserting "or a DACA recipient (as defined in section 1312(f)(3))" after "an alien lawfully present in the United States".

(c) APPLICATION OF TAX CREDIT FOR COVERAGE UNDER A QUALIFIED HEALTH PLAN.—Section 36B(c)(2) of the Internal Revenue Code of 1986 is amended by adding at the end the following: "A DACA recipient (as defined in section 1312(f)(3) of the Patient Protection and Affordable Care Act) shall be treated as lawfully present for purposes of this section.".

(f) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2021.

TITLE II—ENCOURAGING MEDICAID EXPANSION AND STRENGTHENING THE MEDICAID PROGRAM

SEC. 201. INCENTIVIZING MEDICAID EXPANSION.

(a) IN GENERAL.—Section 1905(y)(1) of the Social Security Act (42 U.S.C. 1396d(y)(1)) is amended—

(1) in subparagraph (A), by striking "2014, 2015, and 2016" and inserting "each of the first 3

consecutive 12-month periods in which the State provides medical assistance to newly eligible individuals";

(2) in subparagraph (B), by striking "2017" and inserting "the fourth consecutive 12-month period in which the State provides medical assistance to newly eligible individuals";

(3) in subparagraph (C), by striking "2018" and inserting "the fifth consecutive 12-month period in which the State provides medical assistance to newly eligible individuals";

(4) in subparagraph (D), by striking "2019" and inserting "the sixth consecutive 12-month period in which the State provides medical assistance to newly eligible individuals"; and

(5) in subparagraph (E), by striking "2020 and each year thereafter" and inserting "the seventh consecutive 12-month period in which the State provides medical assistance to newly eligible individuals and each such period thereafter".

(b) EFFECTIVE DATE.—Beginning on January 1, 2022, the amendments made by subsection (a) shall take effect as if included in the enactment of the Patient Protection and Affordable Care Act (Public Law 111–148).

SEC. 202. PROVIDING 12-MONTHS OF CONTINUOUS ELIGIBILITY FOR MEDICAID AND CHIP.

(a) REQUIREMENT OF 12-MONTH CONTINUOUS ENROLLMENT UNDER MEDICAID.—Section 1902(e)(12) of the Social Security Act (42 U.S.C. 1396a(e)(12)) is amended to read as follows:

"(12) 12-MONTH CONTINUOUS ENROLLMENT.—Notwithstanding any other provision of this title, a State plan approved under this title (or under any waiver of such plan approved pursuant to section 1115 or section 1915), shall provide that an individual who is determined to be eligible for benefits under such plan (or waiver) shall remain eligible and enrolled for such benefits through the end of the month in which the 12-month period (beginning on the date of determination of eligibility) ends.".

(b) REQUIREMENT OF 12-MONTH CONTINUOUS ENROLLMENT UNDER CHIP.—

(1) IN GENERAL.—Section 2102(b) of the Social Security Act (42 U.S.C. 1397bb(b)) is amended by adding at the end the following new paragraph:

"(6) REQUIREMENT FOR 12-MONTH CONTINUOUS ENROLLMENT.—Notwithstanding any other provision of this title, a State child health plan that provides child health assistance under this title through a means other than described in section

2101(a)(2), shall provide that an individual who is determined to be eligible for benefits under such plan shall remain eligible and enrolled for such benefits through the end of the month in which the 12-month period (beginning on the date of determination of eligibility) ends.".

(2) CONFORMING AMENDMENT.—Section 2105(a)(4)(A) of the Social Security Act (42 U.S.C. 1397ee(a)(4)(A)) is amended—

(A) by striking "has elected the option of" and inserting "is in compliance with the requirement for"; and

(B) by striking "applying such policy under its State child health plan under this title" and inserting "in compliance with section 2102(b)".

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2) or (3), the amendments made by subsections (a) and (b) shall apply to determinations (and redeterminations) of eligibility made on or after the date that is 12 months after the last day of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)).

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX or State child health plan under title XXI of the Social Security Act (42 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.) which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the respective plan to meet the additional requirement imposed by the amendment made by subsection (a) or (b), respectively, the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such applicable additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

(3) OPTION TO IMPLEMENT 12-MONTH CONTINUOUS ELIGIBILITY PRIOR TO EFFECTIVE DATE.—A State may elect through a State plan amendment under title XIX or XXI of the Social Security Act

(42 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.) to apply the amendment made by subsection (a) or (b), respectively, on any date prior to the date specified in paragraph (1), but not sooner than the date of the enactment of this Act.

SEC. 203. MANDATORY 12-MONTHS OF POSTPARTUM MEDICAID ELIGIBILITY.

(a) EXTENDING CONTINUOUS MEDICAID AND CHIP COVERAGE FOR PREGNANT AND POSTPARTUM WOMEN.—

(1) MEDICAID.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended—

(A) in section 1902(l)(1)(A), by striking "60-day period" and inserting "365-day period";

(B) in section 1902(e)(6), by striking "60-day period" and inserting "365-day period";

(C) in section 1903(v)(4)(A)(i), by striking "60-day period" and inserting "365-day period"; and

(D) in section 1905(a), in the 4th sentence in the matter following paragraph (30), by striking "60-day period" and inserting "365-day period".

(2) CHIP.—Section 2112 of the Social Security Act (42 U.S.C. 1397ll) is amended by striking "60-

day period" each place it appears and inserting "365-day period".

(b) REQUIRING FULL BENEFITS FOR PREGNANT AND POSTPARTUM WOMEN.—

(1) MEDICAID.—

(A) IN GENERAL.—Paragraph (5) of section 1902(e) of the Social Security Act (24 U.S.C. 1396a(e)) is amended to read as follows:

"(5) Any woman who is eligible for medical assistance under the State plan or a waiver of such plan and who is, or who while so eligible becomes, pregnant, shall continue to be eligible under the plan or waiver for medical assistance through the end of the month in which the 365-day period (beginning on the last day of her pregnancy) ends, regardless of the basis for the woman's eligibility for medical assistance, including if the woman's eligibility for medical assistance is on the basis of being pregnant.".

(B) CONFORMING AMENDMENT.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended in the matter following subparagraph (G) by striking "(VII) the medical assistance" and all that follows through "complicate pregnancy,".

(2) CHIP.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

(A) by redesignating subparagraphs (H) through (S) as subparagraphs (I) through (T), respectively; and

(B) by inserting after subparagraph (G), the following:

"(H) Section 1902(e)(5) (requiring 365-day continuous coverage for pregnant and postpartum women).".

(c) MAINTENANCE OF EFFORT.—

(1) MEDICAID.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—

(A) in paragraph (74), by striking "subsection (gg); and" and inserting "subsections (gg) and (qq);"; and

(B) by adding at the end the following new subsection:

"(qq) MAINTENANCE OF EFFORT RELATED TO LOW-INCOME PREGNANT WOMEN.—For calendar quarters beginning on or after the effective date described in section 203(d) of the Patient Protection and Affordable Care Enhancement Act, and before January 1, 2023, no Federal payment shall be made to a State under section 1903(a)

for amounts expended under a State plan under this title or a waiver of such plan if the State—

"(1) has in effect under such plan eligibility standards, methodologies, or procedures for individuals described in subsection (l)(1) who are eligible for medical assistance under the State plan or waiver under subsection (a)(10)(A)(ii)(IX) that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, for such individuals under such plan or waiver that are in effect on the date of the enactment of this subsection; or

"(2) provides medical assistance to individuals described in subsection (l)(1) who are eligible for medical assistance under such plan or waiver under subsection (a)(10)(A)(ii)(IX) at a level that is less than the level at which the State provides such assistance to such individuals under such plan or waiver on the date of the enactment of this subsection.".

(2) CHIP.—Section 2112 of the Social Security Act (42 U.S.C. 1397ll), as amended by subsection (b), is further amended by adding at the end the following subsection:

"(g) MAINTENANCE OF EFFORT.—For calendar quarters beginning on or after the effective date described in section 203(d) of the Patient Protection and Affordable

Care Enhancement Act, and before January 1, 2023, no payment may be made under section 2105(a) with respect to a State child health plan if the State—

"(1) has in effect under such plan eligibility standards, methodologies, or procedures for targeted low-income pregnant women that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under such plan that are in effect on the date of the enactment of this subsection; or

"(2) provides pregnancy-related assistance to targeted low-income pregnant women under such plan at a level that is less than the level at which the State provides such assistance to such women under such plan on the date of the enactment of this subsection.".

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided under paragraph (2), the amendments made by subsections (a) and (b) shall take effect on (and the effective date described in this subsection shall be) the first day of the calendar quarter during which the last day of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)) occurs.

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX or State child health plan under title XXI of the Social Security Act (42 U.S.C. 1396 et seq.; 42 U.S.C. 1397aa et seq.) which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the respective plan to meet the additional requirement imposed by the amendments made by subsection (a) or (b), respectively, the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such applicable additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

SEC. 204. REDUCING THE ADMINISTRATIVE FMAP FOR NONEXPANSION STATES.

Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended—

(1) in subsection (a)(7), by inserting "subsection (bb) and" before "section 1919(g)(3)(B)"; and

(2) by adding at the end the following new subsection:

"(bb) REDUCTION OF FEDERAL PAYMENTS FOR CERTAIN ADMINISTRATIVE COSTS OF NONEXPANSION STATES.—

"(1) IN GENERAL.—In the case of a State that does not provide under the State plan of such State (or waiver of such plan) for making medical assistance available in accordance with section 1902(k)(1) to all individuals described in section 1902(a)(10)(i)(VIII) for a calendar quarter beginning on or after October 1, 2022, the Secretary may reduce the percentage specified in subsection (a)(7) for amounts described in such subsection expended during such quarter by such State by the number of percentage points specified in paragraph (2) for such quarter.

"(2) AMOUNT OF REDUCTION.—For purposes of paragraph (1), the number of percentage points

specified in this paragraph for a calendar quarter is the following:

"(A) For the calendar quarter beginning on October 1, 2022, 0.5.

"(B) For a calendar quarter beginning on or after January 1, 2023, and ending before July 1, 2027, the number of percentage points specified under this paragraph for the previous quarter, plus 0.5.

"(C) For a calendar quarter beginning on or after July 1, 2027, 10.

"(3) DEFINITION.—For purposes of this subsection, the term 'State' means a State that is one of the 50 States or the District of Columbia.".

SEC. 205. ENHANCED REPORTING REQUIREMENTS FOR NONEXPANSION STATES.

Section 1903 of the Social Security Act (42 U.S.C. 1396b), as amended by section 204, is further amended—

(1) in subsection (a)(7), by striking "subsection (bb)" and inserting "subsections (bb) and (cc)"; and

(2) by adding at the end the following new subsection:

"(cc) REDUCTION OF FEDERAL PAYMENTS FOR CERTAIN ADMINISTRATIVE COSTS OF NONEXPANSION STATES THAT DO NOT SATISFY REPORTING REQUIREMENTS.—

"(1) IN GENERAL.—

"(A) REDUCTION.—In the case of a non-expansion State, with respect to a fiscal year (beginning with fiscal year 2023) that does not satisfy the reporting requirement under paragraph (2) for such fiscal year, the percentage specified in subsection (a)(7) for amounts described in such subsection expended by such State during a calendar quarter described in paragraph (4) with respect to such fiscal year, subject to subparagraph (B), shall be reduced by the number of percentage points specified in paragraph (4) for the respective calendar quarter.

"(B) EXCEPTION.—In the case of a non-expansion State that is subject to a reduction under subparagraph (A) for the calendar quarter described in paragraph (4)(A) with respect to a fiscal year, if the State satisfies the criteria described in subparagraphs (A), (B), and (C) of paragraph (2) (without regard to the dates specified in such subparagraph (A) and (C)) before the beginning of a subsequent calendar quarter described in paragraph (4) with respect to such fiscal year, then such State shall not be

subject to a reduction under subparagraph (A) for such subsequent calendar quarter.

"(2) REPORTING REQUIREMENT.—For purposes of paragraph (1), a nonexpansion State satisfies the reporting requirement under this paragraph for a fiscal year, if the nonexpansion State—

"(A) by not later than January 1 of such year, posts on the public website of the State agency administering the State plan, the information described in paragraph (3) with respect to such State for the previous year;

"(B) provides for at least a 30-day period for notice and comment on such information; and

"(C) by not later than March 1 of such year, submits to the Secretary a complete report including such information, comments submitted pursuant to subparagraph (B), and a response by the State to each such comment.

"(3) INFORMATION DESCRIBED.—The information described in this paragraph, with respect to a State and year, is the following:

"(A) The the estimated number of individuals who were uninsured for at least 6 months, shown by age-groups of 0 to 18 years of age

and of 19 years of age to 64 years of age, as well as a detailed description of the basis for the estimates.

"(B) The estimated number of the individuals estimated under subparagraph (A) in the State who would be eligible for medical assistance under the State plan if the State were to make medical assistance under the State plan available in accordance with section 1902(k)(1) to all individuals described in section 1902(a)(10)(i)(VIII), and a detailed description of the basis for the estimates.

"(C) A comprehensive listing of State income eligibility criteria for all mandatory and optional Medicaid eligibility groups for which the State plan provides medical assistance (other than with respect to individuals described in clause (i)(II), (ii)(VI), or (ii)(XXII) of section 1902(a)(10)(A)).

"(D) The total amount of hospital uncompensated-care costs and a breakdown of the source of such costs, as well as a breakdown for rural and non-rural hospitals.

"(4) PERCENTAGE DESCRIBED.—For purposes of paragraph (1), a calendar quarter described in

this paragraph, with respect to a fiscal year, and the percentage points described in this paragraph for such quarter, with respect to a State, are—

"(A) for the calendar quarter beginning on the April 1 occurring during such fiscal year, 0.5 percentage points;

"(B) for the calendar quarter beginning on the July 1 occurring during such fiscal year, 1.0 percentage point; and

"(C) for the calendar quarter beginning on the October 1 occurring during the subsequent fiscal year, 1.5 percentage points.

"(5) PAYMENT IN CASE OF REPORTING STATE.—The expenses incurred by a non-expansion State, with respect to any calendar quarter with respect to a fiscal year (beginning with 2021), for carrying out subparagraphs (A) through (C) of paragraph (2) shall, for purposes of section 1903(a)(7), be considered to be expenses necessary for the proper and efficient administration of the State plan under this title.

"(6) NONEXPANION STATE DEFINED.—For purposes of this subsection, the term 'nonexpansion State' means, with respect to a fiscal year, a State that as of the first quarter of such fiscal year does

not provide under the State plan of such State (or waiver of such plan) for making medical assistance available in accordance with section 1902(k)(1) to all individuals described in section 1902(a)(10)(i)(VIII).".

SEC. 206. PRIMARY CARE PAY INCREASE.

(a) RENEWAL OF PAYMENT FLOOR; ADDITIONAL PROVIDERS.—

(1) IN GENERAL.—Section 1902(a)(13) of the Social Security Act (42 U.S.C. 1396a(a)(13)) is amended by striking subparagraph (C) and inserting the following:

"(C) payment for primary care services (as defined in subsection (jj)) at a rate that is not less than 100 percent of the payment rate that applies to such services and physician under part B of title XVIII (or, if greater, the payment rate that would be applicable under such part if the conversion factor under section 1848(d) for the year involved were the conversion factor under such section for 2009), and that is not less than the rate that would otherwise apply to such services under this title if the rate were determined without regard to this subparagraph, and that are—

"(i) furnished during 2013 and 2014, by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine; or

"(ii) furnished during the period that begins on the first day of the first month that begins one year after the date of enactment of the Patient Protection and Affordable Care Enhancement Act and ends September 30, 2024—

"(I) by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine, but only if the physician self-attests that the physician is Board certified in family medicine, general internal medicine, or pediatric medicine;

"(II) by a physician with a primary specialty designation of obstetrics and gynecology, but only if the physician self-attests that the physician is Board certified in obstetrics and gynecology;

"(III) by an advanced practice clinician, as defined by the Secretary, that works under the supervision of—

"(aa) a physician that satisfies the criteria specified in subclause (I) or (II); or

"(bb) a nurse practitioner or a physician assistant (as such terms are defined in section 1861(aa)(5)(A)) who is working in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg)) who is working in accordance with State law;

"(IV) by a rural health clinic, Federally-qualified health center, or other health clinic that receives reimbursement on a fee schedule applicable to a physician, a nurse practitioner or a physician assistant (as such terms are defined in section 1861(aa)(5)(A)) who is working in accordance with State law, or a certified nurse-midwife (as defined in section

1861(gg)) who is working in accordance with State law, for services furnished by a physician, nurse practitioner, physician assistant, or certified nurse-midwife, or services furnished by an advanced practice clinician supervised by a physician described in subclause (I)(aa) or (II)(aa), another advanced practice clinician, or a certified nurse-midwife; or

"(V) by a nurse practitioner or a physician assistant (as such terms are defined in section 1861(aa)(5)(A)) who is working in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg)) who is working in accordance with State law, in accordance with procedures that ensure that the portion of the payment for such services that the nurse practitioner, physician assistant, or certified nurse-midwife is paid is not less than the amount that the nurse practitioner, physician assistant, or certified nurse-midwife would

be paid if the services were provided under part B of title XVIII;".

(2) CONFORMING AMENDMENTS.—Section 1905(dd) of the Social Security Act (42 U.S.C. 1396d(dd)) is amended—

(A) by striking "Notwithstanding" and inserting the following:

"(1) IN GENERAL.—Notwithstanding";

(B) by inserting "or furnished during the additional period specified in paragraph (2)," after "2015,"; and

(C) by adding at the end the following:

"(2) ADDITIONAL PERIOD.—For purposes of paragraph (1), the additional period specified in this paragraph is the period that begins on the first day of the first month that begins one year after the date of enactment of the Patient Protection and Affordable Care Enhancement Act.".

(b) IMPROVED TARGETING OF PRIMARY CARE.—Section 1902(jj) of the Social Security Act (42 U.S.C. 1396a(jj)) is amended—

(1) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively and realigning the left margins accordingly;

(2) by striking "For purposes of" and inserting the following:

"(1) IN GENERAL.—For purposes of"; and

(3) by adding at the end the following:

"(2) EXCLUSIONS.—Such term does not include any services described in subparagraph (A) or (B) of paragraph (1) if such services are provided in an emergency department of a hospital.".

(c) ENSURING PAYMENT BY MANAGED CARE ENTITIES.—

(1) IN GENERAL.—Section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(A) in clause (xii), by striking "and" after the semicolon;

(B) by realigning the left margin of clause (xiii) so as to align with the left margin of clause (xii) and by striking the period at the end of clause (xiii) and inserting "; and"; and

(C) by inserting after clause (xiii) the following:

"(xiv) such contract provides that (I) payments to providers specified in section 1902(a)(13)(C) for primary care services defined in section 1902(jj) that are furnished during a year or period specified

in section 1902(a)(13)(C) and section 1905(dd) are at least equal to the amounts set forth and required by the Secretary by regulation, (II) the entity shall, upon request, provide documentation to the State, sufficient to enable the State and the Secretary to ensure compliance with subclause (I), and (III) the Secretary shall approve payments described in subclause (I) that are furnished through an agreed upon capitation, partial capitation, or other value-based payment arrangement if the capitation, partial capitation, or other value-based payment arrangement is based on a reasonable methodology and the entity provides documentation to the State sufficient to enable the State and the Secretary to ensure compliance with subclause (I).".

(2) CONFORMING AMENDMENT.—Section 1932(f) of the Social Security Act (42 U.S.C. 1396u–2(f)) is amended by inserting "and clause (xiv) of section 1903(m)(2)(A)" before the period.

SEC. 207. PERMANENT FUNDING FOR CHIP.

(a) IN GENERAL.—Section 2104(a) of the Social Security Act (42 U.S.C. 1397dd(a)) is amended—

(1) in paragraph (26), by inserting at the end "and";

(2) by amending paragraph (27) to read as follows:

"(27) for each fiscal year beginning with fiscal year 2024, such sums as are necessary to fund allotments to States under subsections (c) and (m).";

and

(3) by striking paragraph (28).

(b) IN GENERAL.—Section 2104(a)(28) of the Social Security Act (42 U.S.C. 1397dd(a)(28)) is amended to read as follows:

"(28) for fiscal year 2027 and each subsequent year, such sums as are necessary to fund allotments to States under subsections (c) and (m).".

(c) ALLOTMENTS.—

(1) IN GENERAL.—Section 2104(m) of the Social Security Act (42 U.S.C. 1397dd(m)) is amended—

(A) in paragraph (2)(B)(i), by striking ",, 2023, and 2027" and inserting "and 2023";

(B) in paragraph (7)—

(i) in subparagraph (A), by striking "and ending with fiscal year 2027,"; and

(ii) in the flush left matter at the end, by striking "or fiscal year 2026" and in-

serting "fiscal year 2026, or a subsequent even-numbered fiscal year";

(C) in paragraph (9)—

(i) by striking "(10), or (11)" and inserting "or (10)"; and

(ii) by striking "2023, or 2027," and inserting "or 2023"; and

(D) by striking paragraph (11).

(2) CONFORMING AMENDMENT.—Section 50101(b)(2) of the Bipartisan Budget Act of 2018 (Public Law 115–123) is repealed.

SEC. 208. PERMANENT EXTENSION OF CHIP ENROLLMENT AND QUALITY MEASURES.

(a) PEDIATRIC QUALITY MEASURES PROGRAM.—Section 1139A(i)(1) of the Social Security Act (42 U.S.C. 1320b–9a(i)(1)) is amended—

(1) in subparagraph (C), by striking at the end "and";

(2) in subparagraph (D), by striking the period at the end and insert a semicolon; and

(3) by adding at the end the following new subparagraphs:

"(E) for fiscal year 2028, $15,000,000 for the purpose of carrying out this section (other than subsections (e), (f), and (g)); and

"(F) for a subsequent fiscal year, the amount appropriated under this paragraph for the previous fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over such previous fiscal year, for the purpose of carrying out this section (other than subsections (e), (f), and (g)).".

(b) EXPRESS LANE ELIGIBILITY OPTION.—Section 1902(e)(13) of the Social Security Act (42 U.S.C. 1396a(e)(13)) is amended by striking subparagraph (I).

(c) ASSURANCE OF AFFORDABILITY STANDARD FOR CHILDREN AND FAMILIES.—

(1) IN GENERAL.—Section 2105(d)(3) of the Social Security Act (42 U.S.C. 1397ee(d)(3)) is amended—

(A) in the paragraph heading, by striking "THROUGH SEPTEMBER 30, 2027"; and

(B) in subparagraph (A), in the matter preceding clause (i)—

(i) by striking "During the period that begins on the date of enactment of the Patient Protection and Affordable Care Act and ends on September 30, 2027" and inserting "Beginning on the date of the en-

actment of the Patient Protection and Affordable Care Act";

(ii) by striking "During the period that begins on October 1, 2019, and ends on September 30, 2027" and inserting "Beginning on October 1, 2019"; and

(iii) by striking "The preceding sentences shall not be construed as preventing a State during any such periods from" and inserting "The preceding sentences shall not be construed as preventing a State from".

(2) CONFORMING AMENDMENTS.—Section 1902(gg)(2) of the Social Security Act (42 U.S.C. 1396a(gg)(2)) is amended—

(A) in the paragraph heading, by striking "THROUGH SEPTEMBER 30, 2027"; and

(B) by striking "through September 30" and all that follows through "ends on September 30, 2027" and inserting "(but beginning on October 1, 2019,".

(d) QUALIFYING STATES OPTION.—Section 2105(g)(4) of the Social Security Act (42 U.S.C. 1397ee(g)(4)) is amended—

(1) in the paragraph heading, by striking "FOR FISCAL YEARS 2009 THROUGH 2027" and inserting "AFTER FISCAL YEAR 2008"; and

(2) in subparagraph (A), by striking "for any of fiscal years 2009 through 2027" and inserting "for any fiscal year after fiscal year 2008".

(c) OUTREACH AND ENROLLMENT PROGRAM.—Section 2113 of the Social Security Act (42 U.S.C. 1397mm) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by striking "during the period of fiscal years 2009 through 2027" and inserting ", beginning with fiscal year 2009,";

(B) in paragraph (2)—

(i) by striking "10 percent of such amounts" and inserting "10 percent of such amounts for the period or the fiscal year for which such amounts are appropriated"; and

(ii) by striking "during such period" and inserting ", during such period or such fiscal year,"; and

(C) in paragraph (3), by striking "For the period of fiscal years 2024 through 2027, an

amount equal to 10 percent of such amounts" and inserting "Beginning with fiscal year 2024, an amount equal to 10 percent of such amounts for the period or the fiscal year for which such amounts are appropriated"; and

(2) in subsection (g)—

(A) by striking "2017,," and inserting "2017,";

(B) by striking "and $48,000,000" and inserting "$48,000,000"; and

(C) by inserting after "through 2027" the following: ", $12,000,000 for fiscal year 2028, and, for each fiscal year after fiscal year 2028, the amount appropriated under this subsection for the previous fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over such previous fiscal year".

(f) CHILD ENROLLMENT CONTINGENCY FUND.—Section 2104(n) of the Social Security Act (42 U.S.C. 1397dd(n)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A)(ii)—

(i) by striking "and 2024 through 2026" and inserting "beginning with fiscal year 2024"; and

(ii) by striking "2023, and 2027" and inserting ", and 2023"; and

(B) in subparagraph (B)—

(i) by striking "2024 through 2026" and inserting "beginning with fiscal year 2024"; and

(ii) by striking "2023, and 2027" and inserting ", and 2023"; and

(2) in paragraph (3)(A)—

(A) by striking "fiscal years 2024 through 2026" and inserting "beginning with fiscal year 2024"; and

(B) by striking "2023, or 2027" and inserting ", or 2023".

SEC. 209. STATE OPTION TO INCREASE CHILDREN'S ELIGIBILITY FOR MEDICAID AND CHIP.

Section 2110(b)(1)(B)(ii) of the Social Security Act (42 U.S.C. 1397jj(b)(1)(B)(ii)) is amended—

(1) in subclause (II), by striking "or" at the end;

(2) in subclause (III), by striking "and" at the end and inserting "or"; and

(3) by inserting after subclause (III) the following new subclause:

"(IV) at the option of the State, whose family income exceeds the maximum income level otherwise established for children under the State child health plan as of the date of the enactment of this subclause; and".

SEC. 210. MEDICAID COVERAGE FOR CITIZENS OF FREELY ASSOCIATED STATES.

(a) IN GENERAL.—Section 402(b)(2) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1612(b)(2)) is amended by adding at the end the following new subparagraph:

"(G) MEDICAID EXCEPTION FOR CITIZENS OF FREELY ASSOCIATED STATES.—With respect to eligibility for benefits for the designated Federal program defined in paragraph (3)(C) (relating to the Medicaid program), section 401(a) and paragraph (1) shall not apply to any individual who lawfully resides in 1 of the 50 States or the District of Columbia in accordance with the Compacts of Free Association between the Government of the United States and the Governments of the Federated States of Micro-

nesia, the Republic of the Marshall Islands, and the Republic of Palau and shall not apply, at the option of the Governor of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, or American Samoa as communicated to the Secretary of Health and Human Services in writing, to any individual who lawfully resides in the respective territory in accordance with such Compacts.".

(b) EXCEPTION TO 5–YEAR LIMITED ELIGIBILITY.—Section 403(d) of such Act (8 U.S.C. 1613(d)) is amended—

(1) in paragraph (1), by striking "or" at the end;

(2) in paragraph (2), by striking the period at the end and inserting "; or"; and

(3) by adding at the end the following new paragraph:

"(3) an individual described in section 402(b)(2)(G), but only with respect to the designated Federal program defined in section 402(b)(3)(C).".

(c) DEFINITION OF QUALIFIED ALIEN.—Section 431(b) of such Act (8 U.S.C. 1641(b)) is amended—

(1) in paragraph (6), by striking "; or" at the end and inserting a comma;

(2) in paragraph (7), by striking the period at the end and inserting ", or"; and

(3) by adding at the end the following new paragraph:

"(8) an individual who lawfully resides in the United States in accordance with a Compact of Free Association referred to in section 402(b)(2)(G), but only with respect to the designated Federal program defined in section 402(b)(3)(C) (relating to the Medicaid program).".

(d) APPLICATION TO STATE PLANS.—Section 1902(a)(10)(A)(i) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(i)) is amended by inserting after subclause (IX) the following:

"(X) who are described in section 402(b)(2)(G) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 and eligible for benefits under this title by reason of application of such section;".

(e) CONFORMING AMENDMENTS.—Section 1108 of the Social Security Act (42 U.S.C. 1308) is amended—

(1) in subsection (f), in the matter preceding paragraph (1), by striking "subsections (g) and (h) and section 1935(e)(1)(B)" and inserting "subsections (g), (h), and (i) and section 1935(e)(1)(B)"; and

(2) by adding at the end the following:

"(i) EXCLUSION OF MEDICAL ASSISTANCE EXPENDITURES FOR CITIZENS OF FREELY ASSOCIATED STATES.—Expenditures for medical assistance provided to an individual described in section 431(b)(8) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1641(b)(8)) shall not be taken into account for purposes of applying payment limits under subsections (f) and (g).".

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to benefits for items and services furnished on or after the date of the enactment of this Act.

SEC. 211. EXTENSION OF FULL FEDERAL MEDICAL ASSISTANCE PERCENTAGE TO INDIAN HEALTH CARE PROVIDERS.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended—

(1) in subsection (a), by amending paragraph (9) to read as follows:

"(9) clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including—

"(A) such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address; and

"(B) such services provided outside the clinic on the basis of a referral from a clinic administered by an Indian Health Program (as defined in paragraph (12) of section 4 of the Indian Health Care Improvement Act, or an Urban Indian Organization as defined in paragraph (29) of section 4 of such Act that has a grant or contract with the Indian Health Service under title V of such Act;".

(2) in subsection (b), by inserting after "(as defined in section 4 of the Indian Health Care Improvement Act)" the following: "; the Federal medical assistance percentage shall also be 100 per centum with respect to amounts expended as medical assistance for services which are received through an Urban Indian organization (as defined in section 4

of the Indian Health Care Improvement Act) that has a grant or contract with the Indian Health Service under title V of such Act".

(b) EXTENSION OF FULL FEDERAL MEDICAL ASSISTANCE PERCENTAGE TO SERVICES FURNISHED BY NATIVE HAWAIIAN HEALTH CARE SYSTEMS.—

(1) IN GENERAL.—Beginning on the date of enactment of this Act—

(A) for purposes of section 1905(a)(9) of the Social Security Act (42 U.S.C. 1396d(a)(9)), services described in subsection (b) that are furnished in any location shall be deemed to be clinic services; and

(B) notwithstanding section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)), the Federal medical assistance percentage with respect to amounts expended as medical assistance for such services shall be 100 percent.

(2) SERVICES DESCRIBED.—The services described in this subsection are services for which payment is available under the State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) of Hawaii (or any waiver of such plan) that—

(A) are furnished on or after the date of enactment of this Act;

(B) are furnished to an individual who—

(i) is a Native Hawaiian; and

(ii) is eligible for medical assistance under such plan; and

(C) are furnished by an Indian health care provider (as such term is defined in section 1932(h)(4)(A) of the Social Security Act (42 U.S.C. 1396u–2(h)(4)(A)) or a Native Hawaiian health care system (without regard to whether such services are furnished through an Indian Health Service facility).

TITLE III—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

SEC. 301. ESTABLISHING A FAIR DRUG PRICING PROGRAM.

(a) PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART E—FAIR PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

"SEC. 1191. ESTABLISHMENT OF PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a Fair Price Negotiation Program (in this part referred to

as the 'program'). Under the program, with respect to each price applicability period, the Secretary shall—

"(1) publish a list of selected drugs in accordance with section 1192;

"(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1193;

"(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1194; and

"(4) carry out the administrative duties described in section 1196.

"(b) DEFINITIONS RELATING TO TIMING.—For purposes of this part:

"(1) INITIAL PRICE APPLICABILITY YEAR.—The term 'initial price applicability year' means a plan year (beginning with plan year 2023) or, if agreed to in an agreement under section 1193 by the Secretary and manufacturer involved, a period of more than one plan year (beginning on or after January 1, 2023).

"(2) PRICE APPLICABILITY PERIOD.—The term 'price applicability period' means, with respect to a drug, the period beginning with the initial price applicability year with respect to which such drug is a

selected drug and ending with the last plan year during which the drug is a selected drug.

"(3) SELECTED DRUG PUBLICATION DATE.—The term 'selected drug publication date' means, with respect to each initial price applicability year, April 15 of the plan year that begins 2 years prior to such year.

"(4) VOLUNTARY NEGOTIATION PERIOD.—The term 'voluntary negotiation period' means, with respect to an initial price applicability year with respect to a selected drug, the period—

"(A) beginning on the sooner of—

"(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1193 with respect to such drug; or

"(ii) June 15 following the selected drug publication date with respect to such selected drug; and

"(B) ending on March 31 of the year that begins one year prior to the initial price applicability year.

"(c) OTHER DEFINITIONS.—For purposes of this part:

"(1) FAIR PRICE ELIGIBLE INDIVIDUAL.—The term 'fair price eligible individual' means, with respect to a selected drug—

"(A) in the case such drug is furnished or dispensed to the individual at a pharmacy or by a mail order service—

"(i) an individual who is enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title if coverage is provided under such plan for such selected drug; and

"(ii) an individual who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or dispensed; and

"(B) in the case such drug is furnished or administered to the individual by a hospital,

physician, or other provider of services or supplier—

"(i) an individual who is entitled to benefits under part A of title XVIII or enrolled under part B of such title if such selected drug is covered under the respective part; and

"(ii) an individual who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or administered.

"(2) MAXIMUM FAIR PRICE.—The term 'maximum fair price' means, with respect to a plan year during a price applicability period and with respect to a selected drug (as defined in section 1192(c)) with respect to such period, the price published pursuant to section 1195 in the Federal Register for such drug and year.

"(3) AVERAGE INTERNATIONAL MARKET PRICE DEFINED.—

"(A) IN GENERAL.—The terms 'average international market price' and 'AIM price' mean, with respect to a drug, the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit (as defined in paragraph (4)) of the drug for sales of such drug (calculated across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type), as computed (as of the date of publication of such drug as a selected drug under section 1192(a)) in all countries described in clause (ii) of subparagraph (B) that are applicable countries (as described in clause (i) of such subparagraph) with respect to such drug.

"(B) APPLICABLE COUNTRIES.—

"(i) IN GENERAL.—For purposes of subparagraph (A), a country described in clause (ii) is an applicable country described in this clause with respect to a drug if there is available an average price

for any unit for the drug for sales of such drug in such country.

"(ii) COUNTRIES DESCRIBED.—For purposes of this paragraph, the following are countries described in this clause:

"(I) Australia.

"(II) Canada.

"(III) France.

"(IV) Germany.

"(V) Japan.

"(VI) The United Kingdom.

"(4) UNIT.—The term 'unit' means, with respect to a drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed.

"SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS AS SELECTED DRUGS.

"(a) IN GENERAL.—Not later than the selected drug publication date with respect to an initial price applicability year, subject to subsection (h), the Secretary shall select and publish in the Federal Register a list of—

"(1)(A) with respect to an initial price applicability year during 2023, at least 25 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or,

with respect to an initial price applicability year during such period beginning after 2023, the maximum number (if such number is less than 25) of such negotiation-eligible drugs for the year) with respect to such year; and

"(B) with respect to an initial price applicability year during 2024 or a subsequent year, at least 50 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period, the maximum number (if such number is less than 50) of such negotiation-eligible drugs for the year) with respect to such year;

"(2) all negotiation-eligible drugs described in subparagraph (C) of such subsection with respect to such year; and

"(3) all new-entrant negotiation-eligible drugs (as defined in subsection (g)(1)) with respect to such year.

Each drug published on the list pursuant to the previous sentence shall be subject to the negotiation process under section 1194 for the voluntary negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for

any subsequent year during the applicable price applicability period). In applying this subsection, any negotiation-eligible drug that is selected under this subsection for an initial price applicability year shall not count toward the required minimum amount of drugs to be selected under paragraph (1) for any subsequent year, including such a drug so selected that is subject to renegotiation under section 1194.

"(b) SELECTION OF DRUGS.—In carrying out subsection (a)(1) the Secretary shall select for inclusion on the published list described in subsection (a) with respect to a price applicability period, the negotiation-eligible drugs that the Secretary projects will result in the greatest savings to the Federal Government or fair price eligible individuals during the price applicability period. In making this projection of savings for drugs for which there is an AIM price for a price applicability period, the savings shall be projected across different dosage forms and strengths of the drugs and not based on the specific formulation or package size or package type of the drugs, taking into consideration both the volume of drugs for which payment is made, to the extent such data is available, and the amount by which the net price for the drugs exceeds the AIM price for the drugs.

"(c) SELECTED DRUG.—For purposes of this part, each drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a 'selected drug' with respect to such year and each subsequent plan year beginning before the first plan year beginning after the date on which the Secretary determines two or more drug products—

"(1) are approved or licensed (as applicable)—

"(A) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or

"(B) under section 351(k) of the Public Health Service Act using such drug as the reference product; and

"(2) continue to be marketed.

"(d) NEGOTIATION-ELIGIBLE DRUG.—

"(1) IN GENERAL.—For purposes of this part, the term 'negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that meets any of the following criteria:

"(A) COVERED PART D DRUGS.—The drug is among the 125 covered part D drugs (as defined in section 1860D–2(e)) for which there

was an estimated greatest net spending under parts C and D of title XVIII, as determined by the Secretary, during the most recent plan year prior to such drug publication date for which data are available.

"(B) OTHER DRUGS.—The drug is among the 125 drugs for which there was an estimated greatest net spending in the United States (including the 50 States, the District of Columbia, and the territories of the United States), as determined by the Secretary, during the most recent plan year prior to such drug publication date for which data are available.

"(C) INSULIN.—The drug is a qualifying single source drug described in subsection (e)(3).

"(2) CLARIFICATION.—In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1), the Secretary shall, to the extent practicable, use data that is aggregated across dosage forms and strengths of the drug and not based on the specific formulation or package size or package type of the drug.

"(3) PUBLICATION.—Not later than the selected drug publication date with respect to an ini-

tial price applicability year, the Secretary shall publish in the Federal Register a list of negotiation-eligible drugs with respect to such selected drug publication date.

"(c) QUALIFYING SINGLE SOURCE DRUG.—For purposes of this part, the term 'qualifying single source drug' means any of the following:

"(1) DRUG PRODUCTS.—A drug that—

"(A) is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and continues to be marketed pursuant to such approval; and

"(B) is not the listed drug for any drug that is approved and continues to be marketed under section 505(j) of such Act.

"(2) BIOLOGICAL PRODUCTS.—A biological product that—

"(A) is licensed under section 351(a) of the Public Health Service Act, including any product that has been deemed to be licensed under section 351 of such Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, and continues to be marketed under section 351 of such Act; and

"(B) is not the reference product for any biological product that is licensed and continues to be marketed under section 351(k) of such Act.

"(3) INSULIN PRODUCT.—Notwithstanding paragraphs (1) and (2), any insulin product that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act and continues to be marketed under such section 505 or 351, including any insulin product that has been deemed to be licensed under section 351(a) of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and continues to be marketed pursuant to such licensure.

For purposes of applying paragraphs (1) and (2), a drug or biological product that is marketed by the same sponsor or manufacturer (or an affiliate thereof or a cross-licensed producer or distributor) as the listed drug or reference product described in such respective paragraph shall not be taken into consideration.

"(f) INFORMATION ON INTERNATIONAL DRUG PRICES.—For purposes of determining which negotiation-

eligible drugs to select under subsection (a) and, in the case of such drugs that are selected drugs, to determine the maximum fair price for such a drug and whether such maximum fair price should be renegotiated under section 1194, the Secretary shall use data relating to the AIM price with respect to such drug as available or provided to the Secretary and shall on an ongoing basis request from manufacturers of selected drugs information on the AIM price of such a drug.

"(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE DRUGS.—

"(1) IN GENERAL.—For purposes of this part, the term 'new-entrant negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug—

"(A) that is first approved or licensed, as described in paragraph (1), (2), or (3) of subsection (e), as applicable, during the year preceding such selected drug publication date; and

"(B) that the Secretary determines under paragraph (2) is likely to be included as a negotiation-eligible drug with respect to the subsequent selected drug publication date.

"(2) DETERMINATION.—In the case of a qualifying single source drug that meets the criteria described in subparagraph (A) of paragraph (1), with respect to an initial price applicability year, if the wholesale acquisition cost at which such drug is first marketed in the United States is equal to or greater than the median household income (as determined according to the most recent data collected by the United States Census Bureau), the Secretary shall determine before the selected drug publication date with respect to the initial price applicability year, if the drug is likely to be included as a negotiation-eligible drug with respect to the subsequent selected drug publication date, based on the projected spending under title XVIII or in the United States on such drug. For purposes of this paragraph the term 'United States' includes the 50 States, the District of Columbia, and the territories of the United States.

"(h) CONFLICT OF INTEREST.—

"(1) IN GENERAL.—In the case the Inspector General of the Department of Health and Human Services determines the Secretary has a conflict, with respect to a matter described in paragraph (2), the individual described in paragraph (3) shall carry

out the duties of the Secretary under this part, with respect to a negotiation-eligible drug, that would otherwise be such a conflict.

"(2) MATTER DESCRIBED.—A matter described in this paragraph is—

"(A) a financial interest (as described in section 2635.402 of title 5, Code of Federal Regulations (except for an interest described in subsection (b)(2)(iv) of such section)) on the date of the selected drug publication date, with respect the price applicability year (as applicable);

"(B) a personal or business relationship (as described in section 2635.502 of such title) on the date of the selected drug publication date, with respect the price applicability year;

"(C) employment by a manufacturer of a negotiation-eligible drug during the preceding 10-year period beginning on the date of the selected drug publication date, with respect to each price applicability year; and

"(D) any other matter the General Counsel determines appropriate.

"(3) INDIVIDUAL DESCRIBED.—An individual described in this paragraph is—

"(A) the highest-ranking officer or employee of the Department of Health and Human Services (as determined by the organizational chart of the Department) that does not have a conflict under this subsection; and

"(B) is nominated by the President and confirmed by the Senate with respect to the position.

"SEC. 1193. MANUFACTURER AGREEMENTS.

"(a) IN GENERAL.—For purposes of section 1191(a)(2), the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than June 15 following the selected drug publication date with respect to such selected drug, under which—

"(1) during the voluntary negotiation period for the initial price applicability year for the selected drug, the Secretary and manufacturer, in accordance with section 1194, negotiate to determine (and, by not later than the last date of such period and in accordance with subsection (c), agree to) a maximum fair price for such selected drug of the manufacturer in order to provide access to such price—

"(A) to fair price eligible individuals who with respect to such drug are described in sub-

paragraph (A) of section 1191(c)(1) and are furnished or dispensed such drug during, subject to subparagraph (2), the price applicability period; and

"(B) to hospitals, physicians, and other providers of services and suppliers with respect to fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to subparagraph (2), the price applicability period;

"(2) the Secretary and the manufacturer shall, in accordance with a process and during a period specified by the Secretary pursuant to rulemaking, renegotiate (and, by not later than the last date of such period and in accordance with subsection (c), agree to) the maximum fair price for such drug if the Secretary determines that there is a material change in any of the factors described in section 1194(d) relating to the drug, including changes in the AIM price for such drug, in order to provide access to such maximum fair price (as so renegotiated)—

"(A) to fair price eligible individuals who with respect to such drug are described in sub-

paragraph (A) of section 1191(c)(1) and are furnished or dispensed such drug during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

"(B) to hospitals, physicians, and other providers of services and suppliers with respect to fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

"(3) the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided to fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(1), at the pharmacy or by a mail order service at the point-of-sale of such drug;

"(4) the manufacturer, subject to subsection (d), submits to the Secretary, in a form and manner specified by the Secretary—

"(A) for the voluntary negotiation period for the price applicability period (and, if applicable, before any period of renegotiation speci-

fied pursuant to paragraph (2)) with respect to such drug all information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part, including information described in section 1192(f) and section 1194(d)(1); and

"(B) on an ongoing basis, information on changes in prices for such drug that would affect the AIM price for such drug or otherwise provide a basis for renegotiation of the maximum fair price for such drug pursuant to paragraph (2);

"(5) the manufacturer agrees that in the case the selected drug of a manufacturer is a drug described in subsection (c), the manufacturer will, in accordance with such subsection, make any payment required under such subsection with respect to such drug; and

"(6) the manufacturer complies with requirements imposed by the Secretary for purposes of administering the program, including with respect to the duties described in section 1196.

"(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a drug,

until such drug is no longer considered a selected drug under section 1192(c).

"(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS WITHOUT AIM PRICE.—

"(1) IN GENERAL.—In the case of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug and for which an AIM price becomes available beginning with respect to a subsequent plan year during the price applicability period for such drug, if the Secretary determines that the amount described in paragraph (2)(A) for a unit of such drug is greater than the amount described in paragraph (2)(B) for a unit of such drug, then by not later than one year after the date of such determination, the manufacturer of such selected drug shall pay to the Treasury an amount equal to the product of—

"(A) the difference between such amount described in paragraph (2)(A) for a unit of such drug and such amount described in paragraph (2)(B) for a unit of such drug; and

"(B) the number of units of such drug sold in the United States, including the 50 States, the District of Columbia, and the territories of

the United States, during the period described in paragraph (2)(B).

"(2) AMOUNTS DESCRIBED.—

"(A) WEIGHTED AVERAGE PRICE BEFORE AIM PRICE AVAILABLE.—For purposes of paragraph (1), the amount described in this subparagraph for a selected drug described in such paragraph, is the amount equal to the weighted average manufacturer price (as defined in section 1927(k)(1)) for such dosage strength and form for the drug during the period beginning with the first plan year for which the drug is included on the list of negotiation-eligible drugs published under section 1192(d) and ending with the last plan year during the price applicability period for such drug with respect to which there is no AIM price available for such drug.

"(B) AMOUNT MULTIPLIER AFTER AIM PRICE AVAILABLE.—For purposes of paragraph (1), the amount described in this subparagraph for a selected drug described in such paragraph, is the amount equal to 200 percent of the AIM price for such drug with respect to the first plan year during the price applicability period

for such drug with respect to which there is an AIM price available for such drug.

"(d) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) may be used only by the Secretary or disclosed to and used by the Comptroller General of the United States or the Medicare Payment Advisory Commission for purposes of carrying out this part.

"(e) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall, pursuant to rulemaking, specify, in accordance with paragraph (2), the information that must be submitted under subsection (a)(4).

"(2) INFORMATION SPECIFIED.—Information described in paragraph (1), with respect to a selected drug, shall include information on sales of the drug (by the manufacturer of the drug or by another entity under license or other agreement with the manufacturer, with respect to the sales of such drug, regardless of the name under which the drug is sold) in any foreign country that is part of the AIM price. The Secretary shall verify, to the extent practicable,

such sales from appropriate officials of the government of the foreign country involved.

"(f) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under section 1196(c)(1), as applicable, for purposes of administering the program.

"SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.

"(a) IN GENERAL.—For purposes of this part, under an agreement under section 1193 between the Secretary and a manufacturer of a selected drug, with respect to the period for which such agreement is in effect and in accordance with subsections (b) and (c), the Secretary and the manufacturer—

"(1) shall during the voluntary negotiation period with respect to the initial price applicability year for such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1193(a)(1); and

"(2) as applicable pursuant to section 1193(a)(2) and in accordance with the process specified pursuant to such section, renegotiate such maximum fair price for such drug for the purpose described in such section.

"(b) NEGOTIATING METHODOLOGY AND OBJECTIVE.—

"(1) IN GENERAL.—The Secretary shall develop and use a consistent methodology for negotiations under subsection (a) that, in accordance with paragraph (2) and subject to paragraph (3), achieves the lowest maximum fair price for each selected drug while appropriately rewarding innovation.

"(2) PRIORITIZING FACTORS.—In considering the factors described in subsection (d) in negotiating (and, as applicable, renegotiating) the maximum fair price for a selected drug, the Secretary shall, to the extent practicable, consider all of the available factors listed but shall prioritize the following factors:

"(A) RESEARCH AND DEVELOPMENT COSTS.—The factor described in paragraph (1)(A) of subsection (d).

"(B) MARKET DATA.—The factor described in paragraph (1)(B) of such subsection.

"(C) UNIT COSTS OF PRODUCTION AND DISTRIBUTION.—The factor described in paragraph (1)(C) of such subsection.

"(D) COMPARISON TO EXISTING THERAPEUTIC ALTERNATIVES.—The factor described in paragraph (2)(A) of such subsection.

"(3) REQUIREMENT.—

"(A) IN GENERAL.—In negotiating the maximum fair price of a selected drug, with respect to an initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, in the case that the manufacturer of the selected drug offers under the negotiation or renegotiation, as applicable, a price for such drug that is not more than the target price described in subparagraph (B) for such drug for the respective year, the Secretary shall agree under such negotiation or renegotiation, respectively, to such offered price as the maximum fair price.

"(B) TARGET PRICE.—

"(i) IN GENERAL.—Subject to clause (ii), the target price described in this subparagraph for a selected drug with respect to a year, is the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit of such drug for sales of such drug, as computed (across different dosage forms

and strengths of the drug and not based on the specific formulation or package size or package type of the drug) in the applicable country described in section 1191(c)(3)(B) with respect to such drug that, with respect to such year, has the lowest average price for such drug as compared to the average prices (as so computed) of such drug with respect to such year in the other applicable countries described in such section with respect to such drug.

"(ii) SELECTED DRUGS WITHOUT AIM PRICE.—In applying this paragraph in the case of negotiating the maximum fair price of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, or, as applicable, renegotiating the maximum fair price for such drug with respect to a subsequent year during the price applicability period for such drug before the first plan year for which there is an AIM price available for such drug, the target price described in this subparagraph for

such drug and respective year is the amount that is 80 percent of the average manufacturer price (as defined in section 1927(k)(1)) for such drug and year.

"(4) ANNUAL REPORT.—After the completion of each voluntary negotiation period, the Secretary shall submit to Congress a report on the maximum fair prices negotiated (or, as applicable, renegotiated) for such period. Such report shall include information on how such prices so negotiated (or renegotiated) meet the requirements of this part, including the requirements of this subsection.

"(c) LIMITATION.—

"(1) IN GENERAL.—Subject to paragraph (2), the maximum fair price negotiated (including as renegotiated) under this section for a selected drug, with respect to each plan year during a price applicability period for such drug, shall not exceed 120 percent of the AIM price applicable to such drug with respect to such year.

"(2) SELECTED DRUGS WITHOUT AIM PRICE.—In the case of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, for each plan year during the price applicability period before the first

plan year for which there is an AIM price available for such drug, the maximum fair price negotiated (including as renegotiated) under this section for the selected drug shall not exceed the amount equal to 85 percent of the average manufacturer price for the drug with respect to such year.

"(d) CONSIDERATIONS.—For purposes of negotiating and, as applicable, renegotiating (including for purposes of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary, consistent with subsection (b)(2), shall take into consideration the factors described in paragraphs (1), (2), (3), and (5), and may take into consideration the factor described in paragraph (4):

"(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, including as submitted by the manufacturer:

"(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

"(B) Market data for the drug, including the distribution of sales across different programs and purchasers and projected future revenues for the drug.

"(C) Unit costs of production and distribution of the drug.

"(D) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

"(E) Data on patents and on existing and pending exclusivity for the drug.

"(F) National sales data for the drug.

"(G) Information on clinical trials for the drug in the United States or in applicable countries described in section 1191(c)(3)(B).

"(2) INFORMATION ON ALTERNATIVE PRODUCTS.—The following information:

"(A) The extent to which the drug represents a therapeutic advance as compared to existing therapeutic alternatives and, to the extent such information is available, the costs of such existing therapeutic alternatives.

"(B) Information on approval by the Food and Drug Administration of alternative drug products.

"(C) Information on comparative effectiveness analysis for such products, taking into consideration the effects of such products on specific populations, such as individuals with

disabilities, the elderly, terminally ill, children, and other patient populations.

In considering information described in subparagraph (C), the Secretary shall not use evidence or findings from comparative clinical effectiveness research 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. Nothing in the previous sentence shall affect the application or consideration of an AIM price for a selected drug.

"(3) FOREIGN SALES INFORMATION.—To the extent available on a timely basis, including as provided by a manufacturer of the selected drug or otherwise, information on sales of the selected drug in each of the countries described in section 1191(c)(3)(B).

"(4) VA DRUG PRICING INFORMATION.—Information disclosed to the Secretary pursuant to subsection (f).

"(5) ADDITIONAL INFORMATION.—Information submitted to the Secretary, in accordance with a process specified by the Secretary, by other parties

that are affected by the establishment of a maximum fair price for the selected drug.

"(e) REQUEST FOR INFORMATION.—For purposes of negotiating and, as applicable, renegotiating (including for purposes of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufacturer of the drug, with respect to a price applicability period, and other relevant data for purposes of this section—

"(1) the Secretary shall, not later than the selected drug publication date with respect to the initial price applicability year of such period, request drug pricing information from the manufacturer of such selected drug, including information described in subsection (d)(1); and

"(2) by not later than October 1 following the selected drug publication date, the manufacturer of such selected drug shall submit to the Secretary such requested information in such form and manner as the Secretary may require.

The Secretary shall request, from the manufacturer or others, such additional information as may be needed to carry out the negotiation and renegotiation process under this section.

"(f) DISCLOSURE OF INFORMATION.—For purposes of this part, the Secretary of Veterans Affairs may disclose to the Secretary of Health and Human Services the price of any negotiation-eligible drug that is purchased pursuant to section 8126 of title 38, United States Code.

"SEC. 1195. PUBLICATION OF MAXIMUM FAIR PRICES.

"(a) IN GENERAL.—With respect to an initial price applicability year and selected drug with respect to such year, not later than April 1 of the plan year prior to such initial price applicability year, the Secretary shall publish in the Federal Register the maximum fair price for such drug negotiated under this part with the manufacturer of such drug.

"(b) UPDATES.—

"(1) SUBSEQUENT YEAR MAXIMUM FAIR PRICES.—For a selected drug, for each plan year subsequent to the initial price applicability year for such drug with respect to which an agreement for such drug is in effect under section 1193, the Secretary shall publish in the Federal Register—

"(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban con-

sumers (all items; U.S. city average) as of September of such previous year; or

"(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

"(2) PRICES NEGOTIATED AFTER DEADLINE.—In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price in the Federal Register by not later than 30 days after the date such maximum price is so determined.

"SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PROVISIONS.

"(a) ADMINISTRATIVE DUTIES.—

"(1) IN GENERAL.—For purposes of section 1191, the administrative duties described in this section are the following:

"(A) The establishment of procedures (including through agreements with manufacturers under this part, contracts with prescription drug plans under part D of title XVIII and MA–PD plans under part C of such title, and

agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market) under which the maximum fair price for a selected drug is provided to fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(1), at pharmacies or by mail order service at the point-of-sale of the drug for the applicable price period for such drug and providing that such maximum fair price is used for determining cost-sharing under such plans or coverage for the selected drug.

"(B) The establishment of procedures (including through agreements with manufacturers under this part and contracts with hospitals, physicians, and other providers of services and suppliers and agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market) under which, in the case of a selected drug furnished or administered by such a hospital, physician, or other provider of services or supplier to fair price eligible individuals (who with respect to such drug

are described in subparagraph (B) of section 1191(c)(1)), the maximum fair price for the selected drug is provided to such hospitals, physicians, and other providers of services and suppliers (as applicable) with respect to such individuals and providing that such maximum fair price is used for determining cost-sharing under the respective part, plan, or coverage for the selected drug.

"(C) The establishment of procedures (including through agreements and contracts described in subparagraphs (A) and (B)) to ensure that, not later than 90 days after the dispensing of a selected drug to a fair price eligible individual by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

"(i) the lesser of—

"(I) the wholesale acquisition cost of the drug;

"(II) the national average drug acquisition cost of the drug; and

"(III) any other similar determination of pharmacy acquisition

costs of the drug, as determined by the Secretary; and

"(ii) the maximum fair price for the drug.

"(D) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

"(i) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of fair price eligible individuals as the Secretary may specify; and

"(ii) any other discounts.

"(E) The establishment of procedures to enter into appropriate agreements and protocols for the ongoing computation of AIM prices for selected drugs, including, to the extent possible, to compute the AIM price for selected drugs and including by providing that the manufacturer of such a selected drug should provide information for such computation not later than 3 months after the first date of the voluntary negotiation period for such selected drug.

"(F) The establishment of 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 the drug.

"(G) The establishment of procedures to negotiate and apply the maximum fair price in a manner that does not include any dispensing or similar fee.

"(H) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

"(i) fair price eligible individuals who are enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title;

"(ii) fair price eligible individuals who are enrolled under a group health plan or health insurance coverage offered by a health insurance issuer in the individual or group market with respect to which there is an agreement in effect under section 1197; and

"(iii) fair price eligible individuals who are entitled to benefits under part A of title XVIII or enrolled under part B of such title.

"(I) The establishment of a negotiation process and renegotiation process in accordance with section 1194, including a process for acquiring information described in subsection (d) of such section and determining amounts described in subsection (b) of such section.

"(J) The provision of a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, fair price eligible individuals, and the third party with a contract under subsection (c)(1).

"(2) MONITORING COMPLIANCE.—

"(A) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1193, including by establishing a mechanism through which violations of such terms may be reported.

"(B) NOTIFICATION.—If a third party with a contract under subsection (c)(1) determines that the manufacturer is not in compliance with such agreement, the third party shall

notify the Secretary of such noncompliance for appropriate enforcement under section 4192 of the Internal Revenue Code of 1986 or section 1198, as applicable.

"(b) COLLECTION OF DATA.—

"(1) FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescription drug plans under part D of title XVIII and MA–PD plans under part C of such title in a timeframe that allows for maximum fair prices to be provided under this part for selected drugs.

"(2) FROM HEALTH PLANS.—The Secretary may collect appropriate data from group health plans or health insurance issuers offering group or individual health insurance coverage in a timeframe that allows for maximum fair prices to be provided under this part for selected drugs.

"(3) COORDINATION OF DATA COLLECTION.—To the extent feasible, as determined by the Secretary, the Secretary shall ensure that data collected pursuant to this subsection is coordinated with, and not duplicative of, other Federal data collection efforts.

"(c) CONTRACT WITH THIRD PARTIES.—

"(1) IN GENERAL.—The Secretary may enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this part. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

"(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

"(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this part;

"(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this part, as necessary for the manufacturer to fulfill its obligations under this part; and

"(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

"(2) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (1) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this part.

"SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER HEALTH PLANS.

"(a) AGREEMENT TO PARTICIPATE UNDER PROGRAM.—

"(1) IN GENERAL.—Subject to paragraph (2), under the program under this part the Secretary shall be treated as having in effect an agreement with a group health plan or health insurance issuer offering group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), with respect to a price applicability period and a selected drug with respect to such period—

"(A) with respect to such selected drug furnished or dispensed at a pharmacy or by mail order service if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or dispensed; and

"(B) with respect to such selected drug furnished or administered by a hospital, physician, or other provider of services or supplier if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or administered.

"(2) OPTING OUT OF AGREEMENT.—The Secretary shall not be treated as having in effect an agreement under the program under this part with a group health plan or health insurance issuer offering group or individual health insurance coverage with respect to a price applicability period and a selected drug with respect to such period if such a plan or issuer affirmatively elects, through a process specified by the Secretary, not to participate under the program with respect to such period and drug.

"(b) PUBLICATION OF ELECTION.—With respect to each price applicability period and each selected drug with respect to such period, the Secretary and the Secretary of Labor and the Secretary of the Treasury, as applicable, shall make public a list of each group health plan and each health insurance issuer offering group or individual health insurance coverage, with respect to which coverage is provided under such plan or coverage for such drug, that has

elected under subsection (a) not to participate under the program with respect to such period and drug.

"SEC. 1198. CIVIL MONETARY PENALTY.

"(a) VIOLATIONS RELATING TO OFFERING OF MAXIMUM FAIR PRICE.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a plan year during the price applicability period for such drug, that does not provide access to a price that is not more than the maximum fair price (or a lesser price) for such drug for such year—

"(1) to a fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1191(c)(1) and who is furnished or dispensed such drug during such year; or

"(2) to a hospital, physician, or other provider of services or supplier with respect to fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physi-

cian, provider, or supplier and the maximum fair price for such drug for such year.

"(b) VIOLATIONS OF CERTAIN TERMS OF AGREEMENT.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a plan year during the price applicability period for such drug, that is in violation of a requirement imposed pursuant to section 1193(a)(6) shall be subject to a civil monetary penalty of not more than $1,000,000 for each such violation.

"(c) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"SEC. 1199. MISCELLANEOUS PROVISIONS.

"(a) PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this part.

"(b) NATIONAL ACADEMY OF MEDICINE STUDY.—Not later than December 31, 2025, the National Academy of Medicine shall conduct a study, and submit to Congress a report, on recommendations for improvements to the program under this part, including the determination of the limits applied under section 1194(c).

"(c) MEDPAC STUDY.—Not later than December 31, 2025, the Medicare Payment Advisory Commission shall conduct a study, and submit to Congress a report, on the program under this part with respect to the Medicare program under title XVIII, including with respect to the effect of the program on individuals entitled to benefits or enrolled under such title.

"(d) LIMITATION ON JUDICIAL REVIEW.—The following shall not be subject to judicial review:

"(1) The selection of drugs for publication under section 1192(a).

"(2) The determination of whether a drug is a negotiation-eligible drug under section 1192(d).

"(3) The determination of the maximum fair price of a selected drug under section 1194.

"(4) The determination of units of a drug for purposes of section 1191(c)(3).

"(e) COORDINATION.—In carrying out this part with respect to group health plans or health insurance coverage offered in the group market that are subject to oversight by the Secretary of Labor or the Secretary of the Treasury, the Secretary of Health and Human Services shall coordinate with such respective Secretary.

"(f) DATA SHARING.—The Secretary shall share with the Secretary of the Treasury such information as is nec-

essary to determine the tax imposed by section 4192 of the Internal Revenue Code of 1986.

"(g) GAO STUDY.—Not later than December 31, 2025, the Comptroller General of the United States shall conduct a study of, and submit to Congress a report on, the implementation of the Fair Price Negotiation Program under this part.".

(b) APPLICATION OF MAXIMUM FAIR PRICES AND CONFORMING AMENDMENTS.—

(1) UNDER MEDICARE.—

(A) APPLICATION TO PAYMENTS UNDER PART B.—Section 1847A(b)(1)(B) of the Social Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is amended by inserting "or in the case of such a drug or biological that is a selected drug (as defined in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), 106 percent of the maximum fair price (as defined in section 1191(c)(2) applicable for such drug and a plan year during such period" after "paragraph (4)".

(B) EXCEPTION TO PART D NON-INTERFERENCE.—Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) is

amended by inserting ", except as provided under part E of title XI" after "the Secretary".

(C) APPLICATION AS NEGOTIATED PRICE UNDER PART D.—Section 1860D–2(d)(1) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)) is amended—

(i) in subparagraph (B), by inserting ", subject to subparagraph (D)," after "negotiated prices"; and

(ii) by adding at the end the following new subparagraph:

"(D) APPLICATION OF MAXIMUM FAIR PRICE FOR SELECTED DRUGS.—In applying this section, in the case of a covered part D drug that is a selected drug (as defined in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), the negotiated prices used for payment (as described in this subsection) shall be the maximum fair price (as defined in section 1191(c)(2)) for such drug and for each plan year during such period.".

(D) INFORMATION FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS REQUIRED.—

(i) PRESCRIPTION DRUG PLANS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

"(8) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require the sponsor to provide information to the Secretary as requested by the Secretary in accordance with section 1196(b).".

(ii) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

"(E) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Section 1860D–12(b)(8).".

(2) UNDER GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE.—

(A) PHSA.—Part A of title XXVII of the Public Health Service Act is amended by insert-

ing after section 2729 the following new section:

"SEC. 2729A. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

"(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group or individual health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan or coverage—

"(1) the provisions of such part shall apply—

"(A) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plans or coverage offered by such plan or issuer, and to the individuals enrolled under such plans or coverage, during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and

MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

"(B) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plans or coverage offered by such plan or issuers, to the individuals enrolled under such plans or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

"(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-

sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

"(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, such individuals so enrolled in such plans and coverage, and such hospitals, physicians, and other providers and suppliers participating in such plans and coverage.

"(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.".

(B) ERISA.—

(i) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974

(29 U.S.C. 1181 et seq.) is amended by adding at the end the following new section:

"SEC. 716. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

"(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan or coverage—

"(1) the provisions of such part shall apply, as applicable—

"(A) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plans or coverage offered by such plan or issuer, and to the individuals enrolled under such plans or coverage, during such period, with respect to such

selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

"(B) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plans or coverage offered by such plan or issuers, to the individuals enrolled under such plans or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

"(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting an amount not more than the maximum fair price

negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

"(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, and such individuals so enrolled in such plans.

"(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.".

(ii) APPLICATION TO RETIREE AND CERTAIN SMALL GROUP HEALTH PLANS.—Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking

"section 711" and inserting "sections 711 and 716".

(iii) CLERICAL AMENDMENT.—The table of sections for subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following:

"Sec. 716. Fair Price Negotiation Program and application of maximum fair prices.".

(C) IRC.—

(i) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 9816. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

"(a) IN GENERAL.—In the case of a group health plan that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan—

"(1) the provisions of such part shall apply, as applicable—

"(A) if coverage of such selected drug is provided under such plan if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plan, and to the individuals enrolled under such plan during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

"(B) if coverage of such selected drug is provided under such plan if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plan, to the individuals enrolled under such plan, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and

other providers and suppliers participating under title XVIII during such period;

"(2) the plan shall apply any cost-sharing responsibilities under such plan, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

"(3) the Secretary shall apply the provisions of such part E to such plan and such individuals so enrolled in such plan.

"(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health plan shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan to not participate in the Fair Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan before the beginning of the plan year for which such election was made.".

(ii) APPLICATION TO RETIREE AND CERTAIN SMALL GROUP HEALTH PLANS.—Section 9831(a)(2) of the Internal Revenue Code of 1986 is amended by inserting "other than with respect to section 9816," before "any group health plan".

(iii) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of such Code is amended by adding at the end the following new item:

"Sec. 9816. Fair Price Negotiation Program and application of maximum fair prices.".

(3) FAIR PRICE NEGOTIATION PROGRAM PRICES INCLUDED IN BEST PRICE AND AMP.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (c)(1)(C)(ii)—

(i) in subclause (III), by striking at the end "; and";

(ii) in subclause (IV), by striking at the end the period and inserting "; and"; and

(iii) by adding at the end the following new subclause:

"(V) in the case of a rebate period and a covered outpatient drug

that is a selected drug (as defined in section 1192(c)) during such rebate period, shall be inclusive of the price for such drug made available from the manufacturer during the rebate period by reason of application of part E of title XI to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States."; and

(B) in subsection (k)(1)(B), by adding at the end the following new clause:

"(iii) CLARIFICATION.—Notwithstanding clause (i), in the case of a rebate period and a covered outpatient drug that is a selected drug (as defined in section 1192(c)) during such rebate period, any reduction in price paid during the rebate period to the manufacturer for the drug by a wholesaler or retail community pharmacy described in subparagraph (A) by reason of application of part E of title XI shall be included in the average manufacturer price for the covered outpatient drug.".

(4) FEHBP.—Section 8902 of title 5, United States Code, is amended by adding at the end the following:

"(p) A contract may not be made or a plan approved under this chapter with any carrier that has affirmatively elected, pursuant to section 1197 of the Social Security Act, not to participate in the Fair Price Negotiation Program established under section 1191 of such Act for any selected drug (as that term is defined in section 1192(c) of such Act).".

(5) OPTION OF SECRETARY OF VETERANS AFFAIRS TO PURCHASE COVERED DRUGS AT MAXIMUM FAIR PRICES.—Section 8126 of title 38, United States Code, is amended—

(A) in subsection (a)(2), by inserting ", subject to subsection (j)," after "may not exceed";

(B) in subsection (d), in the matter preceding paragraph (1), by inserting ", subject to subsection (j)" after "for the procurement of the drug"; and

(C) by adding at the end the following new subsection:

"(j)(1) In the case of a covered drug that is a selected drug, for any year during the price applicability period for

such drug, if the Secretary determines that the maximum fair price of such drug for such year is less than the price for such drug otherwise in effect pursuant to this section (including after application of any reduction under subsection (a)(2) and any discount under subsection (c)), at the option of the Secretary, in lieu of the maximum price (determined after application of the reduction under subsection (a)(2) and any discount under subsection (c), as applicable) that would be permitted to be charged during such year for such drug pursuant to this section without application of this subsection, the maximum price permitted to be charged during such year for such drug pursuant to this section shall be such maximum fair price for such drug and year.

"(2) For purposes of this subsection:

"(A) The term 'maximum fair price' means, with respect to a selected drug and year during the price applicability period for such drug, the maximum fair price (as defined in section 1191(c)(2) of the Social Security Act) for such drug and year.

"(B) The term 'negotiation eligible drug' has the meaning given such term in section 1192(d)(1) of the Social Security Act.

"(C) The term 'price applicability period' has, with respect to a selected drug, the meaning given such term in section 1191(b)(2) of such Act.

"(D) The term 'selected drug' means, with respect to a year, a drug that is a selected drug under section 1192(c) of such Act for such year.".

SEC. 302. DRUG MANUFACTURER EXCISE TAX FOR NON-COMPLIANCE.

(a) IN GENERAL.—Subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE PERIODS.

"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—

"(1) such tax, divided by

"(2) the sum of such tax and the price for which so sold.

"(b) NONCOMPLIANCE PERIODS.—A day is described in this subsection with respect to a selected drug if it is a day during one of the following periods:

"(1) The period beginning on the June 16th immediately following the selected drug publication date and ending on the first date during which the manufacturer of the drug has in place an agreement described in subsection (a) of section 1193 of the Social Security Act with respect to such drug.

"(2) The period beginning on the April 1st immediately following the June 16th described in paragraph (1) and ending on the first date during which the manufacturer of the drug has agreed to a maximum fair price under such agreement.

"(3) In the case of a selected drug with respect to which the Secretary of Health and Human Services has specified a renegotiation period under such agreement, the period beginning on the first date after the last date of such renegotiation period and ending on the first date during which the manufacturer of the drug has agreed to a renegotiated maximum fair price under such agreement.

"(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under such agreement, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

"(5) In the case of a selected drug with respect to which a payment is due under subsection (c) of such section 1193, the period beginning on the date on which the Secretary of Health and Human Services certifies that such payment is overdue and ending on the date that such payment is made in full.

"(c) APPLICABLE PERCENTAGE.—For purposes of this section, the term 'applicable percentage' means—

"(1) in the case of sales of a selected drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

"(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

"(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

"(4) in the case of sales of such drug during any subsequent day, 95 percent.

"(d) SELECTED DRUG.—For purposes of this section—

"(1) IN GENERAL.—The term 'selected drug' means any selected drug (within the meaning of section 1192 of the Social Security Act) which is manu-

factured or produced in the United States or entered into the United States for consumption, use, or warehousing.

"(2) UNITED STATES.—The term 'United States' has the meaning given such term by section 4612(a)(4).

"(3) COORDINATION WITH RULES FOR POSSESSIONS OF THE UNITED STATES.—Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

"(e) OTHER DEFINITIONS.—For purposes of this section, the terms 'selected drug publication date' and 'maximum fair price' have the meaning given such terms in section 1191 of the Social Security Act.

"(f) ANTI-ABUSE RULE.—In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).".

(b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—Section 275 of the Internal Revenue Code of 1986 is amended by adding "or by section 4192" before the period at the end of subsection (a)(6).

(c) CONFORMING AMENDMENTS.—

(1) Section 4221(a) of the Internal Revenue Code of 1986 is amended by inserting "or 4192" after "section 4191".

(2) Section 6416(b)(2) of such Code is amended by inserting "or 4192" after "section 4191".

(d) CLERICAL AMENDMENTS.—

(1) The heading of subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by striking "**Medical Devices**" and inserting "**Other Medical Products**".

(2) The table of subchapters for chapter 32 of such Code is amended by striking the item relating to subchapter E and inserting the following new item:

"SUBCHAPTER E. OTHER MEDICAL PRODUCTS".

(3) The table of sections for subchapter E of chapter 32 of such Code is amended by adding at the end the following new item:

"Sec. 4192. Selected drugs during noncompliance periods.".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enactment of this Act.

SEC. 303. FAIR PRICE NEGOTIATION IMPLEMENTATION FUND.

(a) IN GENERAL.—There is hereby established a Fair Price Negotiation Implementation Fund (referred to in

this section as the "Fund"). The Secretary of Health and Human Services may obligate and expend amounts in the Fund to carry out this title (and the amendments made by such title).

(b) FUNDING.—There is authorized to be appropriated, and there is hereby appropriated, out of any monies in the Treasury not otherwise appropriated, to the Fund $3,000,000,000, to remain available until expended, of which—

(1) $600,000,000 shall become available on the date of the enactment of this Act;

(2) $600,000,000 shall become available on October 1, 2020;

(3) $600,000,000 shall become available on October 1, 2021;

(4) $600,000,000 shall become available on October 1, 2022; and

(5) $600,000,000 shall become available on October 1, 2023.

(c) SUPPLEMENT NOT SUPPLANT.—Any amounts appropriated pursuant to this section shall be in addition to any other amounts otherwise appropriated pursuant to any other provision of law.

TITLE IV—PUBLIC HEALTH INVESTMENTS

SEC. 401. SUPPORTING INCREASED INNOVATION.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall continue to support and to expand, as applicable, biomedical research carried out through the National Institutes of Health innovation projects described in section 1001(b)(4) of the 21st Century Cures Act (Public Law 114–255). The Secretary shall ensure that any such research (and related activities) is conducted in compliance with section 492B of the Public Health Service Act (42 U.S.C. 289a–2) (relating to the inclusion of women and members of minority groups in research).

(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, in addition to funds made available under paragraph (2) of section 1001(b) of the 21st Century Cures Act (Public Law 114–255), there is authorized to be appropriated, and there is appropriated to the NIH Innovation Account established under such section 1001(b), out of any moneys in the Treasury not otherwise

obligated, $2,000,000,000 for fiscal year 2021, to remain available until expended.

Passed the House of Representatives June 29, 2020.

Attest: CHERYL L. JOHNSON,

Clerk.

Case 4:24-cv-00783-SDJ Document 3-6 Filed 08/29/24 Page 161 of 165 PageID #: 1534

Calendar No. 523

116TH CONGRESS
2D SESSION

H. R. 1425

AN ACT

To amend the Patient Protection and Affordable Care Act to provide for a Improve Health Insurance Affordability Fund to provide for certain reinsurance payments to lower premiums in the individual health insurance market.

SEPTEMBER 8, 2020

Read the second time and placed on the calendar

U.S. GOVERNMENT INFORMATION GPO

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117TH CONGRESS
1ST SESSION

H. R. 1875

To amend title XXVII of the Public Health Service Act to eliminate the short-term limited duration insurance exemption with respect to individual health insurance coverage.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 2021

Ms. CASTOR of Florida (for herself and Mr. HIGGINS of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XXVII of the Public Health Service Act to eliminate the short-term limited duration insurance exemption with respect to individual health insurance coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ELIMINATING THE SHORT-TERM LIMITED DURATION INSURANCE EXEMPTION WITH RESPECT TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Section 2791(b)(5) of the Public Health Service Act (42 U.S.C. 300gg–91(b)(5)) is amended by inserting

"(other than such insurance that is issued, sold, or renewed on or after January 1, 2023)" before the period at the end.

○

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

116TH CONGRESS
1ST SESSION

S. 1556

To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect.

IN THE SENATE OF THE UNITED STATES

MAY 21, 2019

Ms. BALDWIN (for herself, Mr. JONES, Mr. BENNET, Mr. BLUMENTHAL, Mr. BOOKER, Mr. BROWN, Ms. CANTWELL, Mr. CARDIN, Mr. CARPER, Mr. CASEY, Mr. COONS, Ms. CORTEZ MASTO, Ms. DUCKWORTH, Mr. DURBIN, Mrs. FEINSTEIN, Mrs. GILLIBRAND, Ms. HARRIS, Ms. HASSAN, Mr. HEINRICH, Ms. HIRONO, Mr. KAINE, Mr. KING, Ms. KLOBUCHAR, Mr. LEAHY, Mr. MANCHIN, Mr. MARKEY, Mr. MENENDEZ, Mr. MERKLEY, Mr. MURPHY, Mrs. MURRAY, Mr. PETERS, Mr. REED, Ms. ROSEN, Mr. SANDERS, Mr. SCHATZ, Mr. SCHUMER, Mrs. SHAHEEN, Ms. SINEMA, Ms. SMITH, Ms. STABENOW, Mr. TESTER, Mr. UDALL, Mr. VAN HOLLEN, Mr. WARNER, Ms. WARREN, Mr. WHITEHOUSE, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide that the rule entitled "Short-Term, Limited Duration Insurance" shall have no force or effect.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "No Junk Plans Act".

SEC. 2. SHORT-TERM LIMITED DURATION INSURANCE RULE PROHIBITION.

The Secretary of Health and Human Services, the Secretary of the Treasury, and the Secretary of Labor may not take any action to implement, enforce, or otherwise give effect to the rule entitled "Short-Term, Limited Duration Insurance" (83 Fed. Reg. 38212 (August 3, 2018)), and the Secretaries may not promulgate any substantially similar rule.

○

Grp. Ex. 5

PATTY MURRAY, WASHINGTON
ROBERT P. CASEY, JR., PENNSYLVANIA
TAMMY BALDWIN, WISCONSIN
CHRISTOPHER MURPHY, CONNECTICUT
TIM KAINE, VIRGINIA
MARGARET WOOD HASSAN, NEW HAMPSHIRE
TINA SMITH, MINNESOTA
BEN RAY LUJÁN, NEW MEXICO
JOHN W. HICKENLOOPER, COLORADO
EDWARD J. MARKEY, MASSACHUSETTS

BILL CASSIDY, LOUISIANA
RAND PAUL, KENTUCKY
SUSAN M. COLLINS, MAINE
LISA MURKOWSKI, ALASKA
MIKE BRAUN, INDIANA
ROGER MARSHALL, KANSAS
MITT ROMNEY, UTAH
TOMMY TUBERVILLE, ALABAMA
MARKWAYNE MULLIN, OKLAHOMA
TED BUDD, NORTH CAROLINA

WARREN GUNNELS, MAJORITY STAFF DIRECTOR
AMANDA LINCOLN, REPUBLICAN STAFF DIRECTOR

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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

February 21, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Janet Yellen
Secretary
Department of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

The Honorable Julie A. Su
Acting Secretary
Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Dear Secretary Becerra, Secretary Yellen, and Acting Secretary Su:

In 2019, then-Presidential candidate Joe Biden promised: "If you like your health care plan, your employer-based plan, you can keep it. In fact[,] if you have private insurance, you can keep it."[1] Despite this promise, the Department of Health and Human Services, the Department of the Treasury, and the Department of Labor ("the Departments") issued a proposed rule on July 12, 2023, to limit Short-Term Limited Duration Insurance (STLDI) plans and fixed indemnity benefits.

The proposed rule breaks the President's promise to the millions of patients who depend on these plans and is tone-deaf as Americans face unprecedentedly high health care costs.[2] Patients buying

[1] Nathaniel Weixel, *Biden: If you like your private health insurance, 'you can keep it'*, The Hill (July 15, 2019), https://thehill.com/policy/healthcare/453173-biden-if-you-like-your-private-health-insurance-you-can-keep-it/.
[2] *CBO's Estimates of Enrollment in Short-Term, Limited-Duration Insurance,* Congressional Budget Office (Sept. 25, 2020), https://www.cbo.gov/publication/56622. *How CBO and JCT Analyzed Coverage Effects of New Rules for*

coverage in the individual market face record-high out-of-pocket limits of $9,450 for an individual and $18,900 for a family, nearly 16% increases since 2020.[3] The annual deductible for a silver plan in the individual market is $5,000 on average, which is roughly double the cost of the average deductible in high-deductible health plans.[4] It is clear that the latest victim of "Bidenomics" is Americans' health care coverage.[5]

STLDI and fixed indemnity plans provide important options to help patients facing such high health care costs obtain essential medical care. Perplexingly, the administration seems intent on eliminating these options for patients, forcing individuals and families into plans that are more expensive and less tailored to their needs.

Short-Term Limited Duration Insurance Plans

STLDI plans provide coverage and benefits for a defined period of time, currently up to three years. This gives patients the flexibility to purchase these plans for a duration of time suited to their specific coverage needs. These plans may offer coverage for the same type of health care services as traditional insurance; however, they are able to do so at a fraction of the cost, as they are not subject to the heavy regulation imposed on plans offered on the Affordable Care Act (ACA) exchanges.

In the preamble to the proposed rule, the Departments assume that the main reason a family would choose a short-term medical plan is if a health insurance broker improperly directed them to one of these plans.[6] The Departments ignore evidence to the contrary. A U.S. Government Accountability Office (GAO) report that examined the sale of STLDI plans through representatives listed on HealthCare.gov noted that, "None of the sales representatives we

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Association Health Plans and Short-Term Plans, Congressional Budget Office (Jan. 31, 2019), https://www.cbo.gov/publication/54915.

[3] *Out-of-pocket maximum/limit,* HealthCare.gov, https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit#:~:text=The%20out%2Dof%2Dpocket%20limit%20for%20Marketplace%20plans%20varies%2C,and%20%2418%2C900%20for%20a%20family. Matthew Rae et al., *ACA's maximum out-of-pocket limit is growing faster than wages,* Peterson-KFF Health System Tracker (July 20, 2022), https://www.healthsystemtracker.org/brief/aca-maximum-out-of-pocket-limit-is-growing-faster-than-wages/#Cumulative%20percent%20change%20from%202014%20in%20HSA-qualified%20maximum%20OOP%20limit,%20ACA%20maximum%20OOP%20limit,%20and%20wages.

[4] *2022 Employer Health Benefits Survey*, KFF (Oct. 27, 2022), https://www.kff.org/report-section/ehbs-2022-section-8-high-deductible-health-plans-with-savings-option/. *Explaining Health Care Reform: Questions About Health Insurance Subsidies,* KFF (Oct. 6, 2023), https://www.kff.org/health-reform/issue-brief/explaining-health-care-reform-questions-about-health-insurance-subsidies/#:~:text=For%20example%2C%20in%202023%2C%20the,a%20platinum%20plan%20was%20%2445.

[5] *2023 Employer Health Benefits Survey*, KFF (Oct. 18, 2023), https://www.kff.org/health-costs/report/2023-employer-health-benefits-survey/.

[6] Short-Term, Limited Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance, (proposed July 12, 2023) (to be codified at 26 C.F.R. pt. 1, 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 144, 45 C.F.R. pt. 146, 45 C.F.R. pt. 148).

contacted engaged in potentially deceptive marketing practices that misrepresented or omitted information about the products they were selling."[7]

Patients are not coerced into purchasing these plans. In direct contrast to the Departments' assumption, American patients opt for this type of coverage because it meets their needs or provides greater value than the other health care options on the market – even heavily-regulated ACA plans. STLDI plans are not for every patient, but they are hardly "junk insurance." They can offer equivalent coverage with lower premiums, cover a larger share of medical costs than the individual market, have lower deductibles or wider provider networks than plans in the fully regulated nongroup market, and attract higher-quality providers through higher payment rates.[8]

The Departments also raise the concern that STLDI plans negatively impact the individual market risk pool and raise premiums for all patients. However, an analysis following the implementation of the Trump administration's 2018 final rule found that in states that fully permitted STLDI plans, all patients experienced improvements in 1) their states' individual markets, 2) the choice of plans available, and 3) the cost of plan premiums on the ACA exchanges.[9]

Paradoxically, the Departments' proposed rule will lead to *fewer* protections for patients, especially those who develop health conditions while enrolled in these plans. Under current rules, a patient with STLDI who develops a costly health condition can renew for 12, 24, or 36 months, ensuring continued health coverage at agreed-to costs. Under the Departments' proposed rule, a patient would be limited to three months of coverage, a one-month renewal, and then coverage is terminated until the next open-enrollment period begins. When the Obama administration enforced similar limitations, patients were unable to obtain additional coverage after the expiration of their STLDI plan, in certain cases racking up hundreds of thousands of dollars in medical bills as a result.[10]

Independent, Non-coordinated Excepted Benefits ("Fixed Indemnity") Coverage

Fixed indemnity plans are a type of voluntary insurance intended to help individuals bridge the gap between coverage provided by major medical insurance and the total out of pocket costs faced by individuals after insurance benefits are applied. The benefits of fixed indemnity plans are critical for patients who experience an unexpected medical emergency or life-threatening

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[7] *Private Health Coverage: Results of Covert Testing for Selected Sales Representatives Listed on Healthcare.gov,* U.S. Government Accountability Office (Aug. 10, 2021), https://www.gao.gov/assets/gao-21-568r.pdf.

[8] Chris Pope, *Renewable Term Health Insurance: Better Coverage Than Obamacare*, Manhattan Institute (May 16, 2019), https://manhattan.institute/article/renewable-term-health-insurance. *How CBO and JCT Analyzed Coverage Effects of New Rules for Association Health Plans and Short-Term Plans*, Congressional Budget Office (Jan. 2019), https://www.cbo.gov/system/files/2019-01/54915-New_Rules_for_AHPs_STPs.pdf.

[9] Brian Blase, *Individual Health Insurance Markets Improving in States that Fully Permit Short-Term Plans*, The Galen Institute (Feb. 2021), https://galen.org/assets/Individual-Health-Insurance-Markets-Improving-in-States-that-Fully-Permit-Short-Term-Plans.pdf.

[10] Michael Cannon, *Biden's new plan threatens health coverage for more than half a million people,* The Hill (July 10, 2023), https://thehill.com/opinion/healthcare/4087396-bidens-new-plan-threatens-health-coverage-for-more-than-half-a-million-people/.

diagnosis. In a recent survey, 90 percent of respondents indicated that a fixed indemnity plan helped pay for necessary medical expenses and eased concerns about financial security.[11]

The Departments' proposed rule restricts the way patients can use fixed indemnity benefits, prohibiting their course of treatment or hospitalization from factoring into the benefit received. Additionally, the Departments propose to prevent patients from coordinating these benefits with other health coverage. These changes disregard the very purpose of fixed indemnity plans and reflect a basic misunderstanding as to how patients use these plans.

Regardless of the aforementioned objections to the proposed changes to fixed indemnity excepted benefits, the Department of the Treasury ("Treasury") lacks the necessary authority to unilaterally propose changes to the tax treatment of fixed indemnity benefits.[12]

Treasury has noted in administration budget proposals not once, but twice, that such changes require legislation rather than regulation. Given that Congress has not taken legislative action to achieve such proposal, it is not within Treasury's authority to now promulgate regulations in what has been previously acknowledged as requiring a legislative change.[13] We urge Treasury to reevaluate what authority it possesses in promulgating regulations for purposes the agency has noted as needing a legislative solution enacted by Congress.

We seek to ensure that the Departments have considered the full consequences of the proposed policies prior to the finalization of this rule. In pursuit of this goal, please respond on a **question-by-question basis**, to the below questions, by **Wednesday, March 6, 2024.**

1. With respect to individuals whose STLDI coverage will be terminated after four months, please provide the following:
    a. Estimates of the total number of individuals enrolled in an STLDI plan who would be without coverage upon the end of the four-month contract period allowed under the proposed rule.
    b. Actions the Departments plan to take to ensure that individuals detailed in 1(a) will not be forced to go without coverage upon the end of their STLDI contract.
2. If the Departments consulted enrollees in STLDI or fixed indemnity plans about the changes included in the proposed rule, please provide specific types of coverage in which individuals were enrolled in and their feedback in a deidentified manner.
    a. If the Departments did not consult individuals currently enrolled in STLDI or fixed indemnity coverage, please detail why the Departments found it appropriate to not directly consult current enrollees affected by the proposed rule.

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[11] *Measuring Satisfaction with Supplemental Insurance*, AHIP (Feb. 23, 2022). https://www.ahip.org/documents/AHIP-Supplemental-Insurance-Deck-032422.pdf

[12] Current law allows these payments to be excluded from gross income as long as the payment does not exceed the actual medical expenses.

[13] *General Explanations of the Administration's Fiscal Year 2023 Revenue Proposals.* The Department of the Treasury (Mar. 2022), https://home.treasury.gov/system/files/131/General-Explanations-FY2023.pdf. *General Explanations of the Administration's Fiscal Year 2024 Revenue Proposals*, The Department of the Treasury, (Mar. 2023), https://home.treasury.gov/system/files/131/General-Explanations-FY2024.pdf.

3. With respect to the Departments' concern regarding STLDI plans impact on adverse selection for risk pools in the individual market, please answer the following:
    a. Please detail the studies or analyses, excluding prospective models, that the Departments considered as sufficient evidence for the proposed changes when examining STLDI plan impact on adverse selection in the individual market risk pools.
    b. Please detail how the Departments anticipate the proposed rule to directly impact the individual market risk pool, including:
        i. The estimated number of individuals enrolling in coverage on the ACA marketplaces, and thus entering the exchange risk pool, who would have otherwise been enrolled in an STLDI plan.
        ii. The estimated change in the number of uninsured individuals, with specific regard to those who may have been previously enrolled in STLDI coverage.
    c. Please detail how the Departments expect the limitation on STLDI coverage to impact premiums for plan year 2025 in the individual market.
        i. Should the proposed rule result in higher plan premiums for the plan year following finalization of the proposed rule, will the Departments reverse the limitation on STLDI coverage?
4. How many individuals do the Departments estimate will enroll in an ACA plan and will receive enhanced premium subsidies provided under the Inflation Reduction Act (IRA), which are set to expire at the end of 2025?
5. With respect to the Treasury's change in tax treatment for fixed indemnity excepted benefits, please answer the following:
    a. The amount of increased tax revenue the Treasury expects to receive as a result of the change in the tax treatment of fixed indemnity benefits. Please also express this as the amount by which impacted individuals' take-home pay will decrease by dollar amount as a result of this change.
    b. The average amount of fixed indemnity benefits received by the plan enrollee, expressed as a dollar amount and percentage, as a result of the change in the tax treatment of such benefits.
    c. The average change in fixed indemnity benefits received by the plan enrollee, expressed as a dollar amount and percentage, as a result of the change in the tax treatment of such benefits.
6. With respect to the Treasury's authority to promulgate regulations addressing the tax treatment for fixed indemnity excepted benefits, please answer the following:
    a. Please detail the Treasury's change in interpretation of the measures required, whether legislative or regulatory, needed to achieve the proposed change of the tax treatment of fixed indemnity excepted benefits. Please ensure that this answer thoroughly elaborates on the legislative change proposed in the General Explanations of the administration's FY 2023 and FY 2024 Revenue Proposals and the subsequent regulatory change included in the Departments' proposed rule, and how the Treasury's understanding of the needed measures changed from requiring a legislative change to regulatory guidance.

b. Please provide justification for Treasury's authority to promulgate regulations that address the treatment of fixed indemnity excepted benefits under the IRC section 105(b). In your answer, please detail how the Treasury is appropriately exercising authority to implement a legislative change that it had previously delegated to Congress.

Sincerely,

Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health, Education, Labor, and Pensions

Mike Braun
U.S. Senator

SEP 1 4 2023

TRINIDAD NAVARRO
COMMISSIONER

STATE OF DELAWARE
DEPARTMENT OF INSURANCE

September 11, 2023

The Honorable Xavier Becerra
Secretary
US Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

The Honorable Lisa Gomez
Assistant Secretary
US Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

The Honorable Janet L. Yellen
Secretary
US Department of Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

RE: Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance Proposed Rules [CMS-9904-P]

Dear Secretary Becerra, Assistant Secretary Gomez, and Secretary Yellen:

As the Commissioner of Insurance for the State of Delaware, I appreciate the opportunity to provide these comments regarding the rule recently proposed by The Department of Health and Human Services, the Department of Labor, and the Department of Treasury (the Tri-Agencies) regarding Short-Term, Limited-Duration Insurance; Independent, Non-coordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance (the Proposed Regulation).

I am primarily writing this letter as the lead regulator in Delaware responsible for assuring that consumers have access to insurance products that afford financial security and well-being to Delaware residents and their families. However, I also chair the National Association of Insurance Commissioners (NAIC) Anti-fraud (D) Task Force. In that role, I oversee the development of model laws, regulations, and state collaboration to identify and solve the specific types of problems identified in the Proposed Regulation. We work on a broad range of consumer protection issues,

and oversee a subgroup called the Improper Marketing of Health Insurance working group. This working group is tackling the issue of improper marketing, sales, lead generation, and product presentation of non-ACA insurance products such as Short-Term, Limited Duration insurance and limited HIPAA-excepted benefits. This is the appropriate place for development of solutions to the problem of improper marketing and sales.

My state regulator colleagues and I have been working through the NAIC in various work streams and in collaboration with federal agencies such as the FTC, FCC, and Justice Department to identify those that are intentionally misrepresenting these products and stop their actions. That is the appropriate process for state and federal governments to collaborate on problem-solving.

I am very concerned that many of the provisions of the Proposed Rule assert federal preemption of state regulatory authority over supplemental insurance benefits and products. The proposed rule creates federal minimum standards that go beyond those used to determine whether they meet the legal requirements for excepted benefit status and leaves no decision-making authority to the states to modify the standards to allow for more flexibility in benefit design.

Congress, through its passage of the McCarron Ferguson Act and subsequent amendments, continues to conclude that the states, by virtue of their expertise and responsibility to consumers, are best suited to regulate the business of insurance as a critically important part of the nation's economy. In passing the Patient Protection and Affordable Care Act of 2010 (the ACA), Congress explicitly recognized the status of hospital indemnity, other fixed indemnity, and specified disease/critical illness benefits as benefits exempted from the Health Insurance Portability and Accountability Act of 1996 and most ACA requirements (HIPAA excepted benefits) and therefore properly regulated by the states. Despite this, the proposed rule further undermines state authority by asserting federal authority to take enforcement actions. At several points in the pre-amble of the proposed rule, the Tri-agencies purport to permit the federal government the authority to exercise enforcement authority over insurers by stating that they will "closely examine as part of potential enforcement actions" whether insurers' fixed indemnity products are in compliance the minimum standards they have established for qualification as a HIPAA excepted benefit. This purported authority to exercise enforcement actions creates a dual regulatory structure and undermines the regulatory integrity and enforcement authority of state insurance regulators. No federal laws alter the jurisdiction of the states over, and responsibility for, insurance regulation; nor enable the dual federal and state regulation of insurance companies' market conduct, minimum standards, and solvency.

There is no statutory text to support many of the major changes being required in the minimum standards for these products. For example, there is no federal law that could remotely be interpreted to limit the benefits payable under fixed indemnity insurance policies to "per time period" nor prohibit "per service" benefits. There is no federal statutory text that prohibits HIPAA excepted benefits from varying benefit amounts based on the severity of diagnosis (e.g. skin cancer versus liver cancer), intensity of treatment or cite of care (e.g. ICU versus observation bed). All of these variations allow insurers to structure products so that they can maintain protective value for those with higher out-of-pocket costs while maintaining affordability of the products by allowing for lower benefit levels for less intense diagnoses or cites of care. There is also no statutory text that prohibits an employer from offering a policy that contains coverage for benefits excluded by a different policy type offered by the same employer.

I cite other concerns with the proposed regulation of a practical nature:

- The proposed rule fails to recognize that fixed indemnity products are often sold to employers or individuals on a guaranteed issue, non-cancellable, or rate-guaranteed basis. This is a contractual promise that the products cannot be canceled or benefits changed or eliminated as long as the policyholder continues to pay premiums, or for a specified time period agreed to by both parties. It is a duty of state regulators to assure that such contractual obligations are fulfilled, and this proposed rule essentially requires that fixed indemnity products sold with those contractual promises in place must be vacated. Enforcement of such a required breach of contract is counter to my obligations as an insurance regulator to protect the residents of my state.
- The proposed rule requires notices and disclosures that do not comport with the notices that state legislatures and regulators have created, often in consultation with consumer advocates and state insurance experts. We recommend flexibility to states in modifying the disclosures based on their expertise.
- The required effective date for compliance for new products and for the disclosure requirements in all products shows a lack of understanding of how state regulatory processes work. The timelines are unrealistic and will place an undue burden on state insurance regulatory agencies across the country.

As a regulator responsible for protecting the people of my state, I strongly urge you to amend the proposed rule to remove the provisions related to hospital indemnity, other fixed indemnity, and specified disease coverage. Those products have been well regulated by states for decades and there is no legal justification for the federal government to create such sweeping changes and assert federal regulatory authority over the fundamental regulatory responsibility for those benefits.

Thank you for your attention and this opportunity to comment on the proposed Tri-Agency rule.

Sincerely,

Trinidad Navarro
Commissioner
Delaware Department of Insurance

cc: The Honorable Thomas R. Carper
The Honorable Christopher A. Coons
The Honorable Lisa Blunt-Rochester
Stephen Benjamin, Senior Advisor and Director of the White House Office of Public Engagement

HEALTH BENEFITS INSTITUTE

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September 11, 2023

Submitted Electronically

Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Attention: CMS-9904-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance [CMS-9904-P]

To Whom It May Concern:

On July 12, 2023, the Departments of Treasury, Labor, and Health and Human Services ("the Departments") published in the *Federal Register* a proposed rule entitled, "Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance" ("proposed rule"). This document proposes to amend the definition of short-term, limited-duration insurance; to amend the requirements for hospital indemnity or other fixed indemnity insurance; and to amend the tax treatment of certain benefit payments in fixed amounts received under employer-provided accident and health plans. In addition, the Departments seek comment on coverage only for a specified disease or illness that qualifies as excepted benefits and level-funded plan arrangements. The Health Benefits Institute (HBI) appreciates the opportunity to comment on the proposed rule.

HBI is a policy organization supported by agents, brokers, insurers, employers, benefit platforms and others seeking to protect the ability of consumers to make their own healthcare financing choices. We support policies that expand consumer choice and control, promote industry standards, educate consumers on their options and foster high quality health outcomes through transparency in healthcare prices, quality, and the financing mechanisms used to pay for care.

HBI's detailed comments are outlined below. These comments align with our shared objectives of promoting consumer choice and accessibility to affordable, quality healthcare coverage. While we commend the Departments for actively seeking comprehensive input regarding the proposed amendments, as described in our comments below, we have serious concerns about many of the proposals in the proposed rule. On balance, if finalized many of the changes would serve to eliminate important coverage options that millions of consumers rely on today, increasing the number of uninsured and resulting in fewer Americans having access to affordable health insurance coverage that meets their needs.

We look forward to engaging with the Departments, including offering further clarification on these comments and providing additional perspectives on the issues that resonate with our members if needed.

Proposed Changes to Short-Term, Limited Duration Insurance (STLDI)

For over two decades, short-term, limited duration insurance (STLDI) has served as a vital, affordable insurance option for many Americans. STLDI fills a critical gap for individuals who are between jobs, those waiting for employer-sponsored insurance to begin, or who are otherwise in need of temporary coverage. The affordability of STLDI is one of its most appealing features. For many consumers, especially those for whom COBRA continuation coverage is too costly, who do not qualify for large subsidies under the ACA, or who miss the marketplace Open Enrollment Period, STLDI is often the only viable alternative to going uninsured. Consumer satisfaction with STLDI is generally high, as these plans offer a range of coverage options that can be tailored to individual needs. STLDI's focus on affordability and customization not only enhances consumer choice but also empowers individuals to take control of their healthcare needs.

The Departments propose to reinterpret the terms "short-term" and "limited-duration" for purposes of STLDI to mean a coverage expiration date not more than three months after the effective date of the final rule and no longer than four months in total, including any renewals or extensions. The Departments also propose that renewals or extensions would include short-term, limited duration policies sold by the same issuer to the same policyholder within 12 months of the original effective date, including the total number of consecutive or nonconsecutive dates of coverage.

States are in the best position to oversee and regulate STLDI

The Departments should recognize that states, not the federal government, are best positioned to regulate STLDI. The 2018 final rule on STLDI sets a minimum federal floor similar to the one set by earlier HIPAA regulations that were in place for nearly two decades. The current federal floor gives states the flexibility to regulate and govern these plans in a manner that best suits their individual markets and consumer needs. In prior rulemaking, the Departments have rightly recognized that states, rather than the federal government, are in the best position to oversee and regulate their own insurance markets. Yet, if finalized as proposed, this rule would impose a one-size-fits all federal approach on the entire country that effectively removes any meaningful state flexibility.

As the Departments point out, since the issuance of the 2018 rule, half of the states have taken action to regulate STLDI in some fashion. This demonstrates the clear ability and willingness of states to effectively regulate these products in their own markets and the lack of a need for new federal regulation. States with less competitive insurance markets where a wide choice of ACA-regulated coverage is not available, for example, may see an advantage in retaining STLDI with a duration of up to 12 months as an option for their consumers—a key reason why half of states have not placed new restrictions on the sale or terms of STDLI.

Furthermore, HBI membership reports very low consumer complaint volume for STLDI products. In the 18-month time period from January 2022 – June 2023, a large short-term medical program of approximately $60 million in annual premiums and 19,200 average in force members over the time period received a total of 40 complaints to the various state departments of insurance—an average complaint rate of 0.012% of monthly subscribers. This indicates a very high (99%+) satisfaction ratio for short-term medical plan consumers in direct contradiction to the Departments' assertions in the proposed rule regarding STLDI.

States have also innovated in this area to make more affordable products available to their citizens. Two states, Idaho and Rhode Island, have taken steps to require STLDI to cover pre-existing conditions, to cover the same categories of health benefits that other nongroup plans must cover, and have made other changes to make STLDI a more attractive alternative for those who cannot afford or cannot otherwise purchase ACA-regulated plans. The actions of these two states, whose market dynamics, political makeups, and populations are very different, illustrate the critical need to continue to allow states to innovate and craft solutions for their

unique market circumstances. The proposed rule would eliminate appropriate state flexibility, harming consumers in Idaho, Rhode Island, and the half of states who have chosen to keep STLDI options available to their residents.

The National Association of Insurance Commissioners (NAIC), representing the chief insurance regulators in all 50 states, the District of Columbia, and the 5 U.S. territories, has consistently asserted that states should be the primary regulators of their insurance markets. In their letter dated August 9, 2016, in response to the Departments' previous proposal to limit the definition of STLDI to 3 months, the NAIC emphasized that federal interference often leads to unintended consequences and may not effectively address underlying issues.[1] The NAIC strongly disagreed with the Departments' proposal in 2016 to limit STLDI to a three-month period, arguing that such a limit would reduce consumer options and could do more harm than good. They pointed out that the proposed rule provided no data to support the premise that a three-month limit would protect consumers or markets. Instead, the NAIC suggested focusing on educating consumers about the limitations of STLDI.[2] The same is true today.

Since the Departments' issuance of the 2016 and 2018 rules, NAIC and its members have taken numerous actions to increase transparency and education around alternative plans like STLDI, hospital indemnity plans, and other fixed indemnity plans. As discussed further below in our comments on hospital indemnity and other fixed indemnity plans, in 2019 NAIC updated its guidance and model act for supplementary and short-term health insurance minimum standards with the goal of standardizing terms, increasing public education, and eliminating confusing or misleading provisions in these forms of coverage.[3] One of the most important recent steps has been to improve data collection on STLDI and hospital indemnity or fixed indemnity plans. Recently, the NAIC updated its Market Conduct Annual Statement (MCAS) standards to require the submission extensive new information on STLDI and hospital indemnity or other fixed indemnity plans, including the data set forth in Table 1 below.[4]

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[1] NAIC comment letter on the Departments' June 10, 2016, proposed rule: "Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance." August 9, 2016 https://content.naic.org/sites/default/files/government-affairs-testimony-letter-hhs-short-term-duration.pdf.

[2] Ibid.

[3] NAIC, "Supplementary and Short-Term Health Insurance Minimum Standards Model Act," https://content.naic.org/sites/default/files/inline-files/MDL-170_0.pdf.

[4] NAIC, "Other Health Insurance Market Conduct Annual Statement Data Call & Definitions," https://content.naic.org/sites/default/files/inline-files/MCAS%20Data%20Call%20Other%20Health%202023.0.1.pdf

Table 1. Selected MCAS "Other Health Insurance" Data Collection

Product Type	Market	Data Collected
Accident only	Individual Trusts/associations Group	• Premiums • Covered lives • Applications and denials • Cancellations • Rescissions • Claims paid, amounts, and denials • Complaints received (both from consumers and DOIs) • Lawsuits • Marketing and sales practices
Hospital/surgical/medical expense		
Hospital/other fixed indemnity		
Specified disease/critical illness		

Regulators who are closely tied to health insurance markets know that information needs to be gathered over a period of time to be properly validated and understood. States need time to be able to review the data and appropriately regulate their markets. The MCAS process not only collects extensive data on the plans, but also uses that data to find outliers, a sort of early regulatory warning system. The Departments have no regulatory authority to collect this data, no ability to analyze the data, and no ability to take regulatory action. In appropriate deference to state activity, the Departments should continue to rely on states and, at a minimum, should not move forward with these regulations until states have been able to collect sufficient data to properly inform policy decisions on these products. In light of these and other concerns raised by this letter, the Departments should not move forward with finalizing the proposed rule at this time.

The Departments have not laid out a reasonable justification for the proposed rule

There is scant evidential basis presented in the proposed rule to justify the heavy-handed federal action contemplated by the Departments. The Departments cite the "low value that STLDI provides to consumers when used as a substitute for comprehensive coverage" while providing little basis for this assertion, nor offering any quantitative data providing insight on the

magnitude of this perceived issue. For example, the Departments provide no survey or other data on the number of consumers enrolling in STLDI plans as a substitute for marketplace coverage or the number of consumers who mistakenly enroll in STLDI under the misapprehension that STLDI represents a lower-cost equivalent to a marketplace plan. Instead, the Departments offer only anecdotes and hypothetical concerns. However, as related in the previous section, states are now moving to collect this data, which is a critical prerequisite to any additional federal or state regulation.

The proposed rule repeatedly cites media articles and blog posts labeling STLDI as "junk insurance" and "problematic," in support of the view that any insurance coverage that is not subject to the ACA's requirements is substandard. Such characterizations are not only unhelpful and inaccurate, but indicate prejudgment and undermine the Departments' mandate to carry out their responsibilities under the PHSA. As the Departments have previously recognized, "short-term, limited-duration insurance plays an important role in providing temporary valuable health coverage to individuals who would otherwise go uninsured. [STLDI] can also provide a more affordable, and potentially desirable, coverage option for some consumers, such as those who cannot afford unsubsidized coverage in the individual market."[5]

Federal law and regulation considers STLDI to be health insurance, as do federal survey instruments like the American Community Survey and the Current Population Survey.[6] The nonpartisan Congressional Budget Office (CBO) has also found STLDI to meet the definition of health insurance for purposes of its projections and estimates of the number of insured Americans. In rejecting Senator Tammy Baldwin's (D-WI) request to recharacterize STLDI as not meeting the definition of health insurance, CBO concluded that, like coverage that is subject to the ACA's nongroup insurance requirements, STLDI "covers high-cost medical events and includes coverage for services provided by physicians and hospitals."[7] Importantly, CBO also found that "[m]ost of the available evidence about STLDI suggesting that it does not constitute health insurance comes from the time before the 2018 rule took effect," that is, while the 2016 rule limiting STLDI to 3-months or less was still in effect. CBO noted that, while the STLDI

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[5] See 83 FR 38217.

[6] See, for example 46 CFR 144.103 ("Health insurance coverage means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage, individual health insurance coverage, and *short-term, limited-duration insurance*." [emphasis added]).

[7] Congressional Budget Office, letter to Senator Tammy Baldwin, September 25, 2020, https://www.cbo.gov/system/files/2020-09/56622-Baldwin.pdf

coverage that was limited to 3-months or less by the 2016 rule "tended to provide coverage for only emergency care and not to provide coverage for preexisting conditions or preventive care," STLDI issued pursuant to the 2018 rule—which allowed initial STLDI terms of up to 12 months—tended to be more comprehensive coverage and to offer a broader array of services than the plans issued under the 2016 rule.

The primary source of the Departments' assertion that STLDI coverage poses significant risks to consumers appears to be blog posts from a single organization (the Commonwealth Fund, which is cited no less than eight times in the preamble to the proposed rule); however, again this organization's studies report only anecdotal concerns about consumer risks. Furthermore, the Departments' examples of specific individuals harmed by these plans are based on media stories, for which the full facts and final disposition of the cases are not provided. Actual data on enrollment numbers and other unbiased data are necessary to determine the real impact on marketplace enrollment and provide a substantive basis upon which to make the sweeping policy changes contemplated by the proposed rule.

ACA coverage is still unaffordable and is not attractive to many Americans

The Departments seek to distinguish STLDI from "comprehensive coverage," a term which is not defined in statute or regulation. The Departments define "comprehensive coverage" as coverage "subject to the Federal [sic] consumer protections and requirements established under chapter 100 of the Internal Revenue Code (Code), part 7 of the Employee Retirement Income Security Act of 1974 (ERISA), and title XXVII of the PHS Act, such as the prohibition of exclusions for preexisting conditions, the prohibition on health status discrimination, the requirement to cover certain preventive services without cost sharing, and many others."

But individual market plans subject to the ACA's consumer protections are in fact often characterized by high deductibles, unaffordable premiums, and narrow networks, making them unaffordable or otherwise unappealing to millions of Americans. The Departments themselves cite a 2022 national survey conducted by the Commonwealth Fund that found 44 percent of individuals with coverage purchased through the ACA-regulated individual market were

considered "underinsured," meaning their coverage did not provide them with affordable access to healthcare despite it being characterized as "comprehensive coverage" by the Departments.[8,9]

While the Departments suggest that increased accessibility and affordability of ACA-regulated individual market coverage since the publication of the 2018 final rules somehow reduces or eliminates the need for STLDI as an option for consumers, access to affordable coverage is still far from universal—and is decreasing for some segments of the population. In 2023, unsubsidized premiums increased on average between 2.2 percent and 4.7 percent compared to the previous year.[10] Today, an unsubsidized 60-year-old couple (non-smoking) seeking to purchase the lowest-cost bronze Qualified Health Plan in their area could pay premiums upwards of $3,000 per month and face maximum out-of-pocket costs of $18,200—putting this coverage out of reach for all but the wealthiest consumers.[11]

Preliminary rate filings for 2024 suggests that rates will continue to rise at a rate higher than overall inflation in the Consumer Price Index (CPI); initial analysis of 320 insurers across the 50 states in DC showed a median proposed premium increase of 6 percent, with almost a quarter of insurers proposing increases over 10 percent.[12] Some states will experience even more significant increases. In Virginia, the end of a state reinsurance program established in 2023 portends estimated premium increases of over 25 percent for residents.[13]

The availability of premium tax credits largely shielded consumers from rate increases in 2023, and the expansion of subsidies under the American Rescue Plan Act (ARPA) has also improved affordability of marketplace coverage for those who qualify for subsidies. However, the availability of expanded subsidies is only temporary and is not guaranteed beyond 2025. Should the temporary increased subsidies under ARPA be allowed to expire, premium costs will spike for marketplace enrollees of all ages and all income levels. Among lower-income individuals

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[8] The survey defined an individual as "underinsured" if they were insured all year but at least one of the following applied: (1) out-of-pocket costs over the prior 12 months, excluding premiums, were equal to 10 percent or more of household income; (2) out-of-pocket costs over the prior 12 months, excluding premiums, were equal to 5 percent or more of household income for individuals living under 200 percent of the federal poverty level ($27,180 for an individual or $55,500 for a family of four in 2022); or (3) the deductible constituted 5 percent or more of household income.

[9] "The State of U.S. Health Insurance in 2022: Findings from the Commonwealth Fund Biennial Health Insurance Survey," Commonwealth Fund, 2022.

[10] "How ACA Marketplace Premiums Are Changing by County in 2023," Kaiser Family Foundation, 2022.

[11] For example, a 60-year-old couple (non-smoking) living in Cabell County, WV would pay $2,961 per month for the lowest-cost bronze plan; the same couple living in La Paz County, AZ would pay $2,351 per month, while if the couple lived in Marion County IL, they would pay $2,447 per in monthly premiums.

[12] "How much and why 2024 premiums are expected to grow in Affordable Care Act Marketplaces," Peterson-KFF Health Systems Tracker, 2023.

[13] Ibid.

who would see subsidy reductions, for example, a single individual making $30,000 (232 percent of the poverty level) would see their monthly premium more than double for an annual increase of $1,320.[14] Because the ARPA also extended subsidies to those with incomes above 400 percent of the federal poverty level, the elimination of the temporary increased subsidies would cause dramatic premium hikes. For example, a typical 60-year-old couple making $75,000 (430 percent of the poverty level) could see monthly marketplace premiums *more than triple*—an annual premium increase of roughly $16,000.[15] Consequently, the continued availability of STLDI will be important to preserving desperately needed coverage options for individuals whose circumstances may change as a result of changing policies and market conditions.

The proposed three-month/four-month limit for STLDI is too brief and will harm consumers

The proposed limitations on the duration of STLDI plans are misaligned with the actual needs of Americans. These restrictions fail to account for the realities of unemployment durations, job search timelines, and the unique circumstances that lead individuals to opt for STLDI plans in the first place. Federal standards for STLDI should, at a minimum, seek to accommodate the average length of unemployment or job search, understanding that many Americans experience much longer periods between jobs or without coverage. This shows a clear need for federal policy to be flexible and to allow a range of coverage options such as STLDI to be available when people need them. Yet, in the name of protecting consumers, the proposed rule would harm consumers by removing options for coverage.

The average duration of a job search greatly exceeds three months, making STLDI a practical solution for maintaining coverage during periods of unemployment. Yet once again, the Departments provide little evidentiary basis for the proposal to limit STLDI to have an expiration date of no more than three months following the effective date and no longer than four months in total.

For example, while the Departments claim that they "reflected on instances when individuals may experience a temporary gap in coverage," they apparently considered only two, highly limited examples–a college student waiting until the fall to enroll in new coverage and a teacher who changes jobs between school years. Yet the length of summer break is in no way representative of how the broader economy works. In fact, according to Department of Labor

[14] "Health Premiums Will Rise Steeply for Millions if Rescue Plan Tax Credits Expire," Center on Budget and Policy Priorities, 2022.
[15] Ibid.

data, the average length of unemployment in the US currently stands at 20.6 weeks–over two months longer than the proposed maximum term of the initial STLDI contract and over one month longer than the proposed total allowable duration including renewals and extensions. As recently as 2011, the average length of unemployment was a full 40.5 weeks, while during the COVID-19 public health emergency, the average length of unemployment spiked to 32 weeks.[16] According to the popular career website Zippia.com, the average length of a job search is five months.[17]

HBI's membership, which includes a number of issuers and marketers of STLDI coverage, reports that the average duration of STLDI is just over seven months.[18] This highlights the fact that consumers have a need for STLDI coverage much longer than three or four months as contemplated by the proposed rule. In addition, since the average duration of enrollment is seven months, this evidence indicates that a significant percentage of consumers remain enrolled in their STLDI plan longer than the average. Data from this HBI member organization indicates that about two-thirds of the enrollment continue past the third month, while over 60 percent continue past the fourth month of coverage. Over the past 18 months, nearly half of enrollees purchased initial durational coverage of 364 days, the maximum allowable under current federal rules. The proposed rule would subject consumers to either not having coverage for periods beyond four months, or in the case where the consumer seeks coverage from a different carrier for an additional four months, potentially being subject to medical underwriting, deductibles, copays, and other out-of-pocket expenses for those additional months.

Moreover, STLDI offers a lifeline for those who miss the Marketplace Annual Open Enrollment Period and do not qualify for a Special Enrollment Period (SEP). Consider the case of Sarah, a 28-year-old freelancer who missed the Open Enrollment window due to a hectic work schedule. She didn't qualify for an SEP because she had no significant life changes like marriage, childbirth, or loss of other coverage. Sarah opted for an STLDI plan, which not only provided her with immediate coverage but was also affordable. The plan's 12-month duration was particularly beneficial as it covered her until the next Open Enrollment Period, saving her from the risk of being uninsured for an extended period.

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[16] U.S. Bureau of Labor Statistics, Average Weeks Unemployed [UEMPMEAN], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/UEMPMEAN, August 27, 2023.
[17] Zippia. "15+ Incredible Job Search Statistics [2023]: What Job Seekers Need To Know" Zippia.com. Feb. 27, 2023, https://www.zippia.com/advice/job-search-statistics/.
[18] This member reported data for a large marketing organization with approximately $60 million in annual premiums.

In addition, should Sarah be diagnosed with a serious illness while enrolled in an STLDI plan with a 364-day initial term, as currently allowed by federal regulations, she would be able to remain in her plan at least until the next Open Enrollment Period; under the Departments' proposed 3-month limit, if Sarah were newly diagnosed with a condition while enrolled in STLDI plan that is not renewable, she may be left uninsured until the next Open Enrollment Period if she does not qualify for an SEP.

Finally, HBI members report that there is no contractual definition that exists today defining a one-month extension. Therefore, there is no rational basis for the Departments proposal to limit STLDI to three months of initial coverage and a one-month extension rather than simply providing for four months of coverage. This proposal is unnecessarily complex and will likely create administrative confusion and impose additional costs. Depending on how the Departments intend to implement the proposed provisions, consumers could be further exposed to additional deductibles or cost sharing for the extension period.

There is no evidence that the current standard is harming the ACA risk pool

The Departments have not provided evidence to support the claim that the existing definition of STLDI negatively impacts premiums or the risk pool in the ACA-regulated individual market. While the Departments cite a 2020 Milliman study to justify limiting STLDI and hospital indemnity or other fixed indemnity plans due to risk pool concerns,[19] a more recent 2023 study by the American Academy of Actuaries contradicts this conclusion. The Academy does not cite STLDI or hospital indemnity or other fixed indemnity plans as significant factors driving premium increases for the 2024 plan year. Furthermore, a 2023 study by the Kaiser Family Foundation reveals that the number of people enrolled in non-ACA-regulated coverage has dropped from 5.7 million in 2015 to an estimated all-time low of only 1.2 million today.[20] This decline has occurred despite Congress "zeroing out" the ACA's individual mandate penalty, which was still in effect in 2015.[21] Given the latest data, rather than the outdated and selective sources relied on

[19] See Dane Hansen and Gabriela Dieguez, "The impact of short-term limited-duration policy expansion on patients and the ACA individual market," Milliman, February 2020 https://www.lls.org/sites/default/files/National/USA/Pdf/STLD-Impact-Report-Final-Public.pdf

[20] Kaiser Family Foundation, "Already at Record High, ACA Marketplace Enrollment Could Increase Further," September 7, 2023, https://www.kff.org/private-insurance/press-release/already-at-record-high-aca-marketplace-enrollment-could-increase-further/.

[21] See Rachel Fehr, Daniel McDermott, and Cynthia Cox, "Individual Insurance Market Performance in 2019," ("[D]espite absence of the mandate penalty, data indicate that the individual market has not become significantly less healthy. These new data from 2019 offer further evidence that the individual market is stable even without a

by the Departments in the preamble, it is evident that concerns about the risk pool do not provide a valid basis for the proposed rule.

The Departments impermissibly substitute their views for the views of Congress in the proposed rule

The exclusion of STLDI from the definition of individual market health insurance (and the ACA's requirements on individual market coverage) was intentional by Congress, not an oversight or mistake. Congress has acted to ensure the availability of comprehensive coverage, but also has repeatedly and intentionally chosen to allow alternative plan options to exist alongside more comprehensive coverage, including renewable STLDI (with an initial contract term of up to 12 months).[22] The proposed rule will effectively do what Congress has chosen not to do by eliminating an affordable option for millions of Americans.

It is also worth noting that, in the wake of several significant healthcare-related actions taken over the last several years in response to the pandemic, Congress has had multiple opportunities to regulate or restrict STLDI but declined to do so. For instance, the Families First Coronavirus Response Act (FFCRA); the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and the No Surprises Act all dealt with critical aspects of health insurance and the individual market. These federal laws touch on various elements relevant to private health insurance coverage in general and individual market coverage in particular, such as coverage requirements, consumer protections, and emergency healthcare provisions. Yet, in none of these legislative actions did Congress choose to include provisions that would limit or regulate STLDI. This omission is not accidental, but rather represents a deliberate choice by Congress to allow STLDI to continue alongside ACA-regulated plans as alternative products. The proposed rule, therefore, not only contradicts the legislative intent but in reality seeks to accomplish what Congress has deliberately refrained from doing for over two decades.

Finally, there is no statutory authority allowing the Departments to take action against private insurance entities for the purpose of protecting ACA-regulated exchange markets from real or imagined adverse selection, nor can the Departments point to any authority allowing them to make alternative insurance products less flexible, flexible, or available to consumers in

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mandate penalty…") https://www.kff.org/private-insurance/issue-brief/individual-insurance-market-performance-in-2019/.

[22] As the Departments said in the 2018 rule: "Indeed, when the federal regulations for short-term, limited-duration insurance were first implemented in 1997, short-term, limited-duration insurance was considered to be health insurance coverage with a period of coverage that was less than 12 months, as under the proposed rule. That standard was in place for nearly two decades without objection." See 83 FR 38216.

order to steer them into the government's preferred health insurance products. As discussed in more detail below in this comment letter, the case of *Central United Life Insurance Co. v Burwell* challenges the Departments' assertions of statutory authority in this area.

Notice Requirements

The Departments propose several modifications to the notice content and specifications for STLDI plans. These changes include requirements for prominent display in both written and electronic formats, the inclusion of a website link and telephone number for HealthCare.gov or the relevant State Exchange website, and State Department of Insurance contact information where applicable. Additionally, the Departments propose adding reminders about eligibility for employer-sponsored coverage.

While clear and comprehensive notice and disclosure requirements are important, these notices must be carefully crafted to avoid confusion. Furthermore, the proposed federal notice requirements could potentially conflict with existing state regulations on the language or placement of such notices. States have their own unique insurance landscapes and consumer protection laws, and their existing notice requirements may already be as prominent, complete, and detailed as the proposed federal requirements. To avoid unnecessary duplication or contradiction, states should be permitted to maintain their existing notice language, provided it meets or exceeds the federal standards in terms of prominence, completeness, and detail.

Applicability and Effective Date

The Departments propose a dual approach to the applicability dates for new and existing short-term, limited-duration coverage. Under this approach, existing policies sold or issued before the final rule's effective date, including any renewals or extensions, would continue to operate under the current Federal definition. In contrast, new policies sold or issued after the effective date would be subject to the Departments' revised definitions. The proposed notice requirements would be applicable to all new policies sold or issued on or after the effective date and would extend to existing policies only in the context of required notices provided upon their renewal or extension.

While the Departments' consideration of transitional periods for currently active policies is appreciated, it is crucial to ensure that the final rule's applicability dates provide issuers with adequate time to make necessary adjustments. This involves updating systems, processes, and vendor relationships, as well as revising notices or materials that may require additional state Department of Insurance review and approval. For both the short-term medical as well as fixed

indemnity market changes, HBI membership reports that typical turnaround times from initial filing of product or rate changes to final approvals by all states are six to nine months, depending on the time of year and whether submissions coincide with the process for submitting rates for qualified health plans (QHPs). When the time needed to update administration and rating systems, processes, and vendor relationships is added, the total timeline is far in excess of the 75-day proposed implementation timeline.

While HBI urges the Departments to withdraw the proposed rule in its entirety, should the Departments finalize this aspect of the proposed rule, we request that the Departments extending the applicability date for the notice requirements to 180 days from the final rule's effective date. While still likely insufficient for some states, this timeline would offer issuers minimal additional time to coordinate with states on updated processes and materials, and to secure any required approvals.

Hospital Indemnity or Other Fixed Indemnity Excepted Benefits Proposals

Millions of middle-income Americans depend on voluntary supplemental insurance products, such as hospital indemnity and other fixed indemnity insurance, to provide financial help with added expenses incurred during and incident to medical problems. Distinct from lost wages, for which disability income insurance provides coverage, hospital indemnity and other fixed indemnity benefits provide coverage for the additional expenses individuals and families face when the individual or a family member requires treatment for a covered illness or medical condition. A few examples of these extraordinary expenses include added childcare expense (due to loss of caregiver), transportation and lodging expenses, home upkeep (repairs, lawn, snow removal, and other functions of daily life that the patient or family members may not be able to provide). Hospital indemnity and other fixed indemnity products may also bridge the financial gap between their comprehensive health plan coverage and the total out-of-pocket expenses they incur during hospitalization or when diagnosed with serious illnesses like cancer. These additional costs can include copays, deductibles, and coinsurance. These expenses can be especially burdensome for lower-income Americans who may have limited or no paid leave and insufficient savings.

Hospital indemnity or other fixed indemnity insurance pays a fixed-dollar benefit that is triggered by a healthcare "event." This benefit is paid directly to the policyholder and is not related to medical expenses incurred. The benefits are commonly used by policyholders to pay

for indirect medical costs and non-medical expenses directly caused by the triggering healthcare event.

The proposed rule marks a significant departure from established federal law. Notably, the last three major congressional actions related to health insurance—HIPAA in 1996, the ACA in 2010, and the No Surprises Act in 2020—all allowed the market for these supplemental products to continue without interruption.

The Departments, without offering any empirical evidence, assert that consumers are confused by "deceptive marketing." However, state insurance regulators have received few complaints regarding consumer confusion surrounding hospital indemnity or other fixed indemnity coverage or consumers mistaking these plans for comprehensive medical coverage. For decades, these regulators have effectively overseen these products and their marketing under existing state laws.

The Departments' proposal, rather than targeting a small and unrepresentative sample of bad actors, would unjustly strip states of their regulatory authority. It would effectively eliminate traditional supplemental insurance products that state regulators have approved for decades and that consumers highly value.

These supplemental plans are not only popular among individuals with employer-sponsored coverage but are also frequently used by other individuals with minimum essential coverage. Individuals enrolled in a silver plan through the marketplace will face an average deductible of over $4,000, money that is not in savings and not available to most Americans. Even seniors enrolled in Medicare Advantage plans need to finance higher cost sharing. These supplemental plans when sold through state licensed insurance companies and state licensed insurance agents help consumers finance these unexpected medical costs.

The Departments' one-size-fits-all approach would needlessly harm these consumers in the name of protecting the ACA-regulated individual market. Moreover, the supplemental policies impacted by the Departments' proposal often come with a "guaranteed renewable" clause, allowing consumers to maintain their existing benefits provided premiums are paid. The proposal would effectively nullify this crucial protection, potentially leaving millions without coverage.[23]

[23] It is worth noting that Medicare and Medicare Advantage serve as effective models of coverage, allowing consumers to opt in or out of supplemental plans at reasonable prices. This is particularly relevant as out-of-pocket healthcare costs continue to rise, outpacing both the Consumer Price Index and wage growth. Hospital indemnity or fixed indemnity products offer a customizable solution to offset these rising costs.

Additionally, the proposal would increase taxes on small businesses and hard-working Americans. Reversing a tax treatment in place for over six decades, the benefits from these supplemental policies would become subject to taxation as wage income if the premiums are paid pre-tax through an employer's cafeteria plan, subject to an increase in FICA taxes for both the employee and the employer.[24]

In summary, the Departments' overreaching approach in the proposed rule would significantly increase Americans' exposure to medical debt and medical bankruptcy, effectively eliminating their ability to secure additional financial protection through these supplemental products.

States have the primary responsibility for regulating insurance markets

As discussed above in our comments on STLDI, state insurance regulators hold the primary responsibility for regulating insurance markets and ensuring consumers are protected. State regulators must retain the flexibility to determine whether, and under what conditions, hospital indemnity or fixed indemnity plans are appropriate for their state. Blanket action at the federal level may not be effective in addressing the underlying issues identified by the Departments and is more likely to have unintended consequences that limits choice and harms consumers.

The states are and have long been the primary authority for regulation of both hospital indemnity and other fixed indemnity insurance. The Public Health Service Act (PHSA) recognizes this authority, and the ACA did not change this authority for these products.[25] Current state law already regulates these products as "supplementary" insurance. The Departments make this proposal despite the successful regulation by the states and state regulators' ongoing support for maintaining "per service" benefit payments.[26]

State regulation includes robust consumer protections and the active enforcement of those protections. Consumer protections include requirements for policy provisions, filing and approval of policy forms, outlines of coverage, marketing, and advertising. State insurance departments monitor compliance with these requirements through consumer complaint

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[24] We note that such a change in federal tax structure might also create additional state tax burdens on employers and employees.

[25] 42 U.S.C. § 300gg-61(a); 65 Fed. Reg. 45,786, 45,787 (1999) ("States are the primary regulators of health insurance coverage in each State.")

[26] See NAIC August 2016 letter commenting on the proposed regulations on Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance.

investigations and market conduct examinations, the MCAS process previously mentioned and may impose fines and order compliance as necessary to enforce requirements. In addition, all state insurance departments have a division for the reporting and investigation of fraud, improper marketing, and other market abuses.

To guide state regulation, the NAIC has adopted a model act (Model #170) for accident and sickness insurance, is currently in the process of updating the corresponding regulation (Model #171) and has also adopted a model regulation (Model #40) that specifically addresses the advertisement of these products. (It is also noteworthy the NAIC first adopted Models #170 and #171 in 1975—21 years before HIPAA was enacted and 35 years prior to the enactment of the ACA.) Many states have adopted or follow the longstanding NAIC model acts and regulations, providing a regulatory framework for these products. Models #170 and #171, which have been frequently updated, contain minimum policy standards, disclosure requirements, as well as an outline of coverage, and other provisions designed to inform consumers of the limited nature of these coverages.

Continuing to recognize the primacy of state regulation of these insurance products and markets allows the flexibility necessary for states to quickly adapt to changing market conditions and tailor state responses appropriate to protect each state's citizens. In deference to appropriate and comprehensive state regulation, the Departments should not move forward with finalizing proposals affecting hospital indemnity or other fixed indemnity plans.

The Departments provide insufficient factual and legal basis for the proposed rule

Once again, the Departments assert significant risks to consumers from hospital indemnity or fixed indemnity excepted benefits coverage without providing appropriate supporting evidence that would justify federal action. Cited sources are heavily anecdotal; one blog post cited by the Departments admits that the authors "are not aware of systematic data on fixed indemnity coverage in the individual or group market."[27] Mere anecdotal evidence is not sufficient justification for federal action on an important issue primarily regulated by the states. Another source cited by the Departments to support claims of misleading marketing draws conclusions from a statistically insignificant sample of only twenty secret shopper phone calls

[27] "Fixed Indemnity Coverage is a Problematic Form of 'Junk' Insurance," U.S.C-Brookings Schaeffer Initiative for Health Policy, 2020.

made in a single state (Texas).[28] Instead of anecdotal evidence, AHIP and ACLI recently surveyed their members and found that the over 4.7 million fixed indemnity members filed 2,432 complaints in 2022[29].

Rather than taking federal, nationwide action, such examples have typically been addressed by state regulators, whose intimate knowledge of their insurance markets enables them to more effectively investigate issues and, if warranted, take appropriate enforcement action or promulgate additional regulations if necessary.

Isolated incidents have occurred where certain consumers may have received misleading or inaccurate information regarding insurance plans, coverage, or benefits. It is important to emphasize that issuers of hospital indemnity or other fixed indemnity plans have no interest in their products being misrepresented to consumers and certainly do not profit from it in any way. Contrary to some assertions, deceptive marketing and sales practices are highly detrimental to insurers both financially and reputationally. Such incidents, even if they are without merit, can incur costs and reputational damage for insurers in the form of the need for increased underwriting, administrative investigations, and loss of trust and goodwill by consumers, distributors, and regulators. Given the relatively low premiums charged for supplemental plans, the time required to recover these increased underwriting and marketing costs can take an extended period of time to recoup, even up to several years. It should be acknowledged by the Departments that insurers have strong incentives to ensure their products are accurately represented in the market.

Excepted benefits are defined under federal law to include hospital indemnity or other fixed indemnity policies, provided the benefits are not coordinated with a group health plan.[30] If these policies meet the three requirements set out in statute, they are treated as excepted benefits and are not subject to federal regulation as comprehensive, major medical health insurance coverage under the PHSA: (a) the "benefits are provided under a separate policy;" (b) there is "no coordination between the provision of such benefits and any exclusion of benefits under" a group health plan by the same sponsor; and (c) the "benefits are paid with respect to an

[28] "Misleading Marketing of Non-ACA Health Plans Continued During COVID-19 Special Enrollment Period," Center on Health Insurance Reforms at Georgetown University, 2021.
[29] Joint-Trade-Survey-Fixed-Indemnity-and-Specified-Disease.pdf (ahiporg-production.s3.amazonaws.com)
[30] 42 U.S.C. §§ 300gg-91(c)(3) (Public Health Service Act (PHSA) § 2191); 300gg-21(c)(2) (PHSA § 2721).

event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor."[31]

This exemption may not be limited through regulation to less than *all* policies encompassed under the statutory requirements. The court in *Central United Life Insurance v. Burwell* made clear the Department did not have authority to establish enrollment in Minimum Essential Coverage (MEC) as a required criterion for individual hospital indemnity or other fixed indemnity policies: "[t]hus, where Congress exempted all such conforming plans from the PHSA's coverage requirements, HHS, with its additional criterion, exempts less than all. Disagreeing with Congress's expressly codified policy choices isn't a luxury administrative agencies enjoy."

Before and after the enactment of the ACA, these products have generally been offered on a per event basis consistent with the statute – *e.g.*, benefits triggered by a healthcare event such as a doctor's visit or hospital stay – and with varying payment amounts. Nothing in the PHSA or the ACA (which did not amend this section or regulate excepted benefits criteria) permits the Departments to add additional criteria for group hospital indemnity or other fixed indemnity insurance to qualify as excepted benefits—including a per day or other time period requirement and restrictions on providing different amounts of payment based on the type of item or service provided. So long as the three statutory conditions are satisfied, the plan qualifies as an excepted benefit.

New criteria for non-coordinated excepted benefit hospital indemnity or other fixed indemnity policies adds requirements not contemplated by the statute and exceeds the Departments' statutory authority and discretion. Under well-settled principles of administrative law, courts apply a two-step analysis to determine whether agencies have overreached their statutory mandate. The first question is always whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, the agency must give effect to the unambiguously expressed intent of Congress. If Congress has not directly addressed the precise question at issue, the question is whether the agency's regulation is based on a permissible construction of the statute.[32]

This is the exact line of reasoning adopted by the D.C. Circuit in *Central United* when a federal regulation attempted to amend the criteria for hospital indemnity or other fixed indemnity insurance in the individual market to be treated as an excepted benefit by requiring

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[31] Id. § 300gg-21(c)(2)(A)-(C).

[32] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

that the plan be "provided only to individuals who have ... minimum essential coverage."[33] Here, as in *Central United*, "Congress has never changed course or put its original definition in any doubt."[34] As a result, in this proposal the Departments lack authority to demand more of hospital indemnity or other fixed indemnity providers than Congress required."[35]

The Departments' proposal presents a radical shift in how a longstanding statute has been interpreted, relied upon, and enforced. Prior to the ACA, the statutory term "event" was understood to always include both per-service and per-period triggers. Neither the ACA nor any other statute changed that common understanding. This underscores the significance of the proposed change and why it is contrary to the statute. Further, the newly proposed criteria for excepted benefits are inconsistent with the Departments' decades-long treatment of these products. The proposed rule would create entirely new, non-statutory requirements that would cause widespread market disruption for a product that has been offered to and purchased by consumers for many years.

Before and following enactment of the excepted benefits statute, insurers, state insurance regulators, and the Departments have shared a common interpretation of the exception for hospital indemnity or other fixed indemnity policies: it does not exclude policies that pay event-based benefits or those that pay varying amounts for different types of services.[36] These new proposed requirements would essentially eliminate the vast majority of hospital indemnity or other fixed indemnity insurance designs offered in the market today.

States have consistently approved policies that pay event-based benefits and allow variation in payments based on service as fixed indemnity or hospital indemnity policies, in line with their responsibilities as primary regulators of the business of insurance and primary enforcers under the PHSA.[37]

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[33] *Central United Life Insur. Co. v. Burwell*, No. 15-5310, 2016 WL 3568084, at *1 (D.C. Cir. Jul. 1, 2016).
[34] Id. at 2.
[35] Id. at 3.
[36] Even the D.C. Circuit, in the *Central United* decision, described fixed indemnity with a "per event" trigger: "Among the excepted benefits listed in the PHSA is a form of insurance known as "fixed indemnity." Id. § 300gg-91(c)(3)(B). As their label suggests, these policies pay out a fixed amount of cash upon the occurrence of a particular medical event. For instance, if a policyholder visits a hospital or purchases prescription drugs, the provider pays out a predetermined amount, which the policyholder is then free to use however she chooses." *Central United* at *1*.
[37] See 42 U.S.C. § 300gg-61(a); 65 Fed. Reg. 45,786, 45,787 (1999) ("States are the primary regulators of health insurance coverage in each State.").

The Departments lack legal authority to limit payments of hospital indemnity or other fixed indemnity benefits to a "per period" basis

Federal statutory authority (HIPAA and ACA) does not employ the terms "per day," or "per period," or "per service" for fixed indemnity benefit amounts. Federal statutory law uses the broader term "events."[38] The phrase "event" is a reference to the various healthcare events that would trigger cash benefit payments under hospital indemnity or other fixed indemnity insurance for uncovered economic expenses. The plain meaning of the phrase "event" would broadly encompass any health-related item or service such as surgery, an emergency room visit, a doctor visit, or the writing of a prescription.

Federal statutes (both HIPAA and the ACA) define "medical care" and "essential health benefits" as consisting of healthcare "items and services." The term "services" is used to describe medical care. The proposed prohibition on a "per service" benefit payment would result in the denial of cash benefit payments to policyholders for many healthcare "events" that are classified as "services."[39]

The HIPAA interim federal rules issued immediately following the enactment of HIPAA used the phrase "per day" only as an example of what is hospital indemnity or other fixed indemnity coverage (*e.g.*, "for example, $100 per day").[40] The HIPAA final rules expanded on the example that it "must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100 per day)".[41] This 2004 amendment remains as the current group market regulation. The preamble explanation for the 2004 amendment does not include any expressed intention to prohibit "per service" based benefit payments.[42]

Furthermore, nowhere in the current federal statute or regulations does any text state that *only* "per day (or other period)" based payments can be utilized as the exclusive basis of benefit payments. In fact, federal regulations have always expressly allowed for payments to be made on either a per period or per service basis. This has been the law since HIPAA's enactment in 1996.

The Departments' proposed ban on "per service" benefits is without statutory authority and contravenes the appellate court's ruling in *Central United*. The states are the primary regulators of insurance and are adequately and appropriately regulating these products, and

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[38] See ERISA Section 705(c)(2); PHSA Section 2721(d)(2).
[39] See ERISA Section 706(a)(1)-(2); PHSA Section 2791(a)(1)-(2); and ACA Section 1302(b).
[40] See *Federal Register* of April 8, 1997.
[41] See FR December 30, 2004.
[42] See 69 FR 78720 at 78735.

federal agencies such as the Federal Trade Commission (FTC) and Federal Communications Commission (FCC) are adequately and appropriately regulating any improper interstate marketing of these products.

In light of these legal concerns and other reasons stated in this comment letter, HBI recommends that the Departments withdraw this proposal.

Income replacement is not the purpose of hospital or other fixed indemnity plans or specified disease products

Throughout the preamble of the proposed rule, the Departments refer to hospital indemnity or other fixed indemnity health insurance plans as "income replacement." HBI disagrees with this categorization. Hospital indemnity or other fixed indemnity plans are most appropriately referenced as a type of supplemental health insurance, as any benefits paid require a health event or the receipt of a health service as a trigger and do not function on a reimbursement basis. As previously discussed herein, benefits provided by fixed indemnity products are intended to cover added expenses incurred during medical encounters. Existing disability income policies already serve that purpose but do not allow for the added costs covered by hospital indemnity or other fixed indemnity insurance.[43] It would be counterproductive and destructive to disqualify hospital indemnity or other fixed indemnity products from regulatory recognition by misrepresenting their purpose.

Consumers purchase hospital indemnity or other fixed indemnity policies as a supplement to their comprehensive major medical plans to cover costs related to their healthcare that they may not have the savings or income to cover. According to recent research on medical billing, about half of American adults are not able to cover a medical bill exceeding $500.[44] Studies examining the financial capabilities of Americans to cover potential healthcare bills generally do not consider patients' or families' ability to pay for the additional costs of sickness or injury that health providers do not bill and major medical health insurers do not pay—such as costs for transportation to and from treatment and childcare. This is where products like hospital

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43 For this discussion, it is useful to reference how disability income products work. For these products, the payment trigger is typically loss of income due to inability to work. However, these products do not require any loss of income from work to pay benefits. Disability income plans also cover individuals who may not even be working at the time, such as children, retirees, or unemployed individuals. Hence, the term "income replacement" is an erroneous oversimplification of how these products work and the benefits they provide to consumers, which extend far beyond mere replacement of income from time spent away from work due to illness, injury, or disability.

44 https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/#:~:text=Main%20takeaways%20include%3A,putting%20off%20due%20to%20cost.

indemnity or other fixed indemnity plans play an invaluable role to help cover out-of-pocket costs for care and other health-related costs that major medical health insurance does not cover. These plans can help policyholders alleviate or avoid medical debt and bankruptcy when used in conjunction with comprehensive major medical plans. The label "supplemental health insurance" is appropriate for these types of plans, while "income replacement" fails to accurately describe these products' structure and function as a complement to comprehensive major medical health insurance.

Prohibitions on benefit variance

The proposed rules would further require that fixed indemnity benefits be paid "regardless of [...] severity of illness or injury experienced by a covered participant or beneficiary, or other characteristics particular to a course of treatment received by a covered participant or beneficiary."

Consideration of the severity and/or level of care is still required to ensure the plans match appropriate benefits to amounts of added costs incurred by members. For instance, the hospital or fixed indemnity benefit paid where a member suffers a broken arm should relate to the likely added costs members incur in such a case. On the other hand, the added costs most often incurred when a family member undergoes long-term treatment for cancer would, in general, be far greater. Specific recognition of diagnosis and severity are integral to preserving the value of fixed indemnity insurance to consumers.

Coordination of Benefits

Noncoordination means that the "excepted benefit" plan may not expressly provide any benefit that is expressly excluded under the group health plan. The effect of this condition is to ensure that supplementary insurance products are not interdependent and a substitute for providing benefits expressly excluded in the primary plan. The prohibited coordination must be real and explicit, not imagined or implied.

Fixed indemnity plans do not provide benefits for specific medical expenses incurred. Instead, specific medical events trigger cash benefit payments that are used to pay for uncovered out-of-pocket expenses for medical items or services and non-medical expenses directly caused by the healthcare event such as transportation, lodging, or other out-of-pocket costs.

The Departments' proposal disregards nearly 30 years of unchallenged understanding about Congress's intentions for the "noncoordination" component of the hospital indemnity or other fixed indemnity benefits definition. In Example (3) under "Special rules relating to group health plans," the proposed rule asserts that a product which provides hospital indemnity or other fixed indemnity benefits for services would "coordinate" if the group plan sponsor has other group health plan coverage which did not provide benefits for those same services. This purported interpretation of the statute is a wholesale reconstruction of its meaning.

There are three requirements making up the "noncoordination" component of hospital indemnity or other fixed indemnity coverage. The first requirement clarifies that the fixed indemnity coverage must stand on its own (*i.e.*, the hospital indemnity or other fixed indemnity benefits are not a part of a traditional major medical policy). As part of HIPPA, this definitional requirement caused traditional group health plans to comply with HIPAA with regard to all facets of the health plan, even where some of the plan benefits were nominally "fixed." The second requirement is that the standalone policy, certificate, and/or contract providing such fixed benefits (referring back to the standalone policy, certificate, and/or contract) does not "coordinate" with any exclusions of another plan of the plan sponsor, which is to say that coverage/benefits under the standalone policy, certificate, and/or contract *cannot be conditioned upon or otherwise take into consideration* the existence of an exclusion in the other plan. This understanding is the only rational understanding of the "noncoordination" language. This is because all insurance is intended to fill holes or gaps (i.e., exclusions). If insurance coverage does not "coordinate" in that sense, then the coverage fails in its fundamental purpose. Moreover, the second requirement, properly understood, is an obvious corollary of the third requirement, which is that the fixed indemnity coverage must pay benefits even if another plan also pays benefits. Read as a whole, all three requirements require "noncoordination," because the fixed indemnity coverage must always pay without regard to provisions in other coverage, the lack of provisions in other coverages, or the existence or non-existence of other coverage.

Finally, the Departments' proposed language on noncoordination lacks specificity and could create significant confusion in the market. Should the Departments choose to finalize these provisions, it could create unintended consequences and could limit beneficial innovation by insurers to offer supplemental products to consumers. In addition, the Departments' related proposal to eliminate assignment of benefits represents an overreach and presents no benefits to consumers.

Notice Requirements

HBI agrees with the Departments that consumers should have a clear understanding of products prior to purchase and supports notice requirements for all supplemental health insurance products. However, HBI supports draft disclosure language prepared by industry representatives, NAIC consumer representatives and state regulators in lieu of the first paragraph of the proposed and alternative notices included in the proposed rules. The disclosures would be required to be included next to the signature on any application or enrollment forms and on the first page of policies and certificates. The language will be included in the final draft of NAIC Model #171, the Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act, and reads as follows:

> (3) For hospital indemnity coverage, the application, policy, and certificate must include a disclosure statement that reads as follows: "This [policy] [certificate] pays fixed dollar benefits as a result of a covered hospitalization due to a sickness or injury. The benefit amounts are not based on the cost of your medical expenses. These benefits are designed to be paid to the [policyholder] [certificate holder]. They are not intended to be paid directly to providers. This [policy] [certificate] is not major medical insurance and does not replace it. Read the description of benefits provided along with your [enrollment form /application] carefully."
>
> **Drafting Note:** The words "fixed dollar benefits" should be prominent.
>
> (4) For other fixed indemnity coverage, the application, policy, and certificate must include a disclosure statement that reads as follows: "This [policy] [certificate] pays fixed dollar benefits as a result of covered events due to a sickness or injury. The benefit amounts are not based on the cost of your medical expenses. These benefits are designed to be paid to the [policyholder] [certificate holder]. They are not intended to be paid directly to providers. This [policy] [certificate] is not major medical insurance and does not replace it. Read the description of benefits provided along with your [enrollment form /application] carefully."

This language is preferrable to the Departments' proposed notice language and reflects the careful consideration of industry, consumer groups, and state regulators.

New Policies and Applicability Dates

For new hospital indemnity or other fixed indemnity health insurance policies sold in both the individual and group markets, HBI is concerned that the proposed applicability dates of 75

days following the publication of the final rule will not allow sufficient time for state legislatures, state regulators, and insurers to implement the new requirements and have products on the market ready for purchase. The effect of these delays would, at very least, prohibit sales of hospital indemnity or other fixed indemnity products of any sort to new enrollees for an undetermined period. The recognized value of hospital indemnity or other fixed indemnity insurance coverage would be lost.

For new individual and group policies conforming with the new requirements to be sold by that time, the following events would need to occur:

- State legislatures would need to pass new minimum standards laws that conform to the new requirements for both the individual and group markets. Minimum standards may include additional requirements or restrictions for hospital indemnity or other fixed indemnity plans to be sold in the state. Additionally, we note that some state legislatures do not meet annually, meaning that it could take more than one year for those states to pass minimum standards legislation and fully implement the new requirements.
- State Departments of Insurance (DOIs) would need to propose, finalize, and implement minimum standards regulations.
- Insurance carriers would need to work internally with benefits experts, actuaries, and accountants to develop new products that are based on sound accounting and actuarial principles and are appealing to individual consumers and employers.
- Insurance carriers would need to submit proposed products to state DOIs for review and approval. Some states also require that any marketing materials for a product be submitted for review and approval.
- State DOIs would need to review and approve insurance carriers' submissions. Given that every carrier will need to re-file every product in the individual and group markets, backlogs will develop in every state. If submissions coincide with the process for submitting rates for qualified health plans (QHPs) in the individual major medical market, review and approval for new hospital indemnity or fixed indemnity products may be delayed as states prioritize QHPs in time for open enrollment.

If states are unable to implement the new rules and insurers are not able to file and receive approval for new products by the 75-day deadline, insurers will be unable to sell any hospital

indemnity or other fixed indemnity policies, leaving consumers without access to a popular supplemental health insurance product.

Existing Policies - Individual Market

In the individual market, hospital indemnity or other fixed indemnity policies are most often sold on a guaranteed renewable basis. When an insurance contract is marketed and sold as guaranteed renewable, provided the policyholder pays their premiums, the contract remains in effect and the benefits cannot change. In some plan designs, the policyholder essentially "pre-funds" the contract by paying a higher premium initially in order to pay a lower premium later (though this is not a universal structure).

As proposed, the requirement to implement the changes for existing policies in the individual market by 2027 would require insurance carriers to violate state contract laws and break contractual promises made to policyholders when their plans were purchased. Beyond the clear conflict with well-established contract law, this proposal would result in significant negative impacts on consumers, who will lose their current robust benefits, which they have continued to find valuable and necessary for their financial protection. Further, if they choose to purchase a new policy, the underwriting for that policy will have to account for their increased age(s), as well as any medical conditions experienced or developed since the original policy was underwritten. Their new policies will likely cost them more, while ultimately providing fewer benefits and less overall value.

For these reasons, HBI strongly opposes the application of the new rules to existing policies sold on a guaranteed renewable basis. Changing the implementation date will not fix this problem.

Existing Policies - Group Market

In the group market, hospital indemnity or other fixed indemnity contracts are generally conditionally or optionally renewable, with timelines that vary in duration. HBI notes that some contracts are subject to collective bargaining agreements (CBAs) that may stretch beyond the proposed 2027 effective date. Requiring those employers to break their CBAs to comply with the new rules is unfair to the workers who rely on their labor organizations to represent them in contract negotiations.

Tax Treatment: Payments from Accident and Health Policies (26 CFR 1.105-2)

The proposed rules include a change to federal tax regulations from the Department of the Treasury and the Internal Revenue Service (IRS) related to the tax treatment of employment-based accident and health insurance plans, which include hospital indemnity or other fixed indemnity and specified disease plans. Under current law, if premiums for these policies are paid by an employer or by the employee with dollars that are excluded from their gross income, then benefits paid under these policies that exceed the cost of medical care should be reported as income by the policyholder.[45] Under the proposed rule, all benefits paid under employment-based polices must be reported as income and subject to both income and payroll taxes (FICA and FUTA are mentioned in the preamble).

HBI opposes this change in long-standing IRS policy and disputes the notion that these changes are a mere "clarification." The tax changes are a significant shift in tax policy that imposes new taxes on working Americans with new burdens on employers. The IRS has previously proposed a similar legislative change in the Fiscal Year 2023 and 2024 President's Budget request and accompanying explanations of revenue proposals ("the Greenbook").[46] Congress has not chosen to implement this requested policy change, and congressional inaction does not grant the Department and the IRS the authority to legislate in its place.

The proposed change would result in a tax increase on hard working Americans, including lower income workers who may have little or no paid leave from work or who may not have savings to cover all expenses, including out-of-pocket expenses under their comprehensive major medical policy. In some instances, the benefits paid in response to an injury or serious illness may shift the policyholder and their household into a higher tax bracket, which could result in an even larger tax increase for that family. Supplemental insurance provides these individuals with financial peace of mind when they are facing a serious injury or illness, and the proposed change makes that peace of mind more expensive and for some, may place it out of reach altogether.

Payouts from other, similar forms of insurance such as life insurance proceeds are not usually taxed. Life insurance proceeds are available to pay for funerals and other related expenses. Similarly, proceeds from fixed indemnity excepted benefits, including hospital indemnity coverage, should not be taxed as income because, regardless of whether such

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[45] 1956-1 CB 63, 70; T.D. 6169

[46] FY 2023: https://home.treasury.gov/system/files/131/General-Explanations-FY2023.pdf
FY 2024: https://home.treasury.gov/system/files/131/General-Explanations-FY2024.pdf

payments are used to pay for medical expenses or other out-of-pocket expenses, they do not make the taxpayer better off financially.

Furthermore, changing the tax treatment of hospital indemnity or other fixed indemnity coverage bears little or no relationship to the Departments' stated goal of distinguishing hospital indemnity or other fixed indemnity coverage from comprehensive coverage. Rather, this proposal represents an inappropriate use of the tax code to promote the Departments' preferred coverage, at the expense of millions of consumers who are benefitting from these supplemental policies. Further, if the proposed change is finalized, insurance providers and employers would face increased administrative burdens, and the proposed rule is unclear as to how the proposed change will be implemented, particularly with respect to payroll tax amounts owed by employers and employees.

Because the IRS lacks statutory authority to make the proposed change and because the proposal breaks the Administration's commitment not to raise taxes on individuals who make less than $400,000 annually, HBI recommends the IRS rescind this proposal in its entirety.

Request for Information on Level-Funded Plans

HBI appreciates the opportunity to provide additional information on level-funded plans, how they operate, the current oversight and regulation of level-funded plans, and the role that agents, brokers, third-party administrators (TPAs), and other benefits advisors and professionals serve with respect to small employer health coverage. Employer-sponsored coverage provides affordable, high-quality coverage options for more than 180 million Americans and their families. Many small employers face additional challenges to provide competitive benefit packages with large employers and have fewer resources to absorb rising healthcare costs. Level-funded plans provide a viable option for small employers to consider when determining whether they can offer health insurance coverage to their workforce.

Small employers may choose to pursue level-funded plan arrangements for a variety of reasons, including costs, employee recruitment and retention, risk tolerance, ability to provide uniform benefits across states, and other factors. Employers who are unwilling or unable to take on level-funding risk, additional compliance requirements, or employers who would prefer to be less involved in the management and monitoring the performance of their benefit plans are not likely to be good candidates for level-funding with stop-loss. In addition, some HBI members report that many small employers who are moving to level-funded plan arrangements previously

offered grandfathered plans under the ACA and were not previously included in the ACA fully-insured small group market.

Level-funded plan designs must comply with many ACA and other federal market reforms, including prohibitions on lifetime and annual limits, out-of-pocket maximums and cost-sharing limits, prohibitions on preexisting condition exclusions, coverage of dependents to age 26, coverage of preventive care without cost sharing, claims appeal requirements, the Transparency in Coverage Rules, the No Surprises Act provisions included in the Consolidated Appropriations Act of 2021 (CAA), and other applicable statutes and regulations.

The proposed rule focuses on a number of issues around level-funded plans and seeks guidance on regulation of level-funded plans. It is important to note that most employers who offer coverage do so regardless of the employer mandate. This is especially true for small businesses – defined as those with fewer than 50 employees – who are not subject to the employer mandate. These small employers face all of the same benefit restrictions that are applied to the individual market but without the subsidies and the mandate to provide coverage. As a result, it has become more and more expensive for employers to provide coverage. The small employer market is already in a death spiral with rising costs and many small employers eliminating health insurance coverage for their employees. This shrinking market has forced more employees into the individual market. The self-funded health market provides a more affordable option for large employers and level funding provides a way for small employers to access the same advantages. Eliminating level funding will merely exacerbate the crisis in the small employer market.

Level-funded plans are a simplified version of other self-funded plans. All self-funded plans have three components: an administrator, stop-loss insurance, and a claims account. The administrator is paid through a fee and controls the checkbook by paying claims and calculating the amount of money an employer must remit to cover costs. Employers also purchase stop-loss insurance to limit the risks both in aggregate and to limit the risk of any one employee who has a single very expensive health event. Finally, the employer is responsible for paying all claims before the reinsurance contract begins to pay. The only differences between level-funded plans and other self-funded insurance plans is that the costs are sent to a single entity to simplify accounting, and the employer is required to pay a fixed amount that reflects the entire risk of their claims account for the year

Level-funded plans are primarily bought by small businesses and offer a lifeline for the declining market. They allow increased flexibility in plan design which helps lower premiums.

Coverage is only offered on a whole-group basis; in other words, all employees are covered or none. If small businesses lose access to level-funded plans, employers who are enrolled in the plans will drop coverage, and employees will move to the individual market.

Level-funded plans have now been available for decades. The *American Medical Security Inc. v. Barlett* which was one of the first versions upholding level-funded plans was decided by the Fourth Circuit in 1997:

> While we recognize that self-funded plans may not be providing Maryland residents with the range of benefits mandated by state law and that such plans' benefits may not always be as secure as those offered by regulated insurance companies, the remedy for any such deficiency must be requested of Congress. When ERISA preempted state law relating to ERISA-covered employee benefit plans, it may have created a regulatory gap, but Maryland is without authority to fill that gap. See Greater Washington Bd. of Trade, 506 U.S. at 130-31, 113 S.Ct. at 583-84 (D.C. workers' compensation provision requiring the provision of benefits in proportion to covered benefits of ERISA plan "relates to" and is therefore preempted by ERISA); Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504, 525, 101 S.Ct. 1895, 1907, 68 L.Ed.2d 402 (1981) ("even indirect state action bearing on [ERISA plans] may encroach upon the area of exclusive federal concern"). This is not to say that Maryland may not regulate stop-loss insurance policies. Such regulation is clearly reserved to the states. See 15 U.S.C. § 1012(a) (The "business of insurance, and every person engaged therein, shall be subject to the laws of the several states"); 29 U.S.C. § 1144(b)(2) (ERISA does not preempt "any law of any State which regulates insurance" unless it deems a plan to be "an insurance company"). But because the Maryland regulation before us attempts to mandate the benefits that certain self-insured plans may offer, we affirm the judgment of the district court.

Based on a plain reading of *AMS v. Bartlett*, the Departments lack the authority to ban level-funded plans or to restrict level-funded employer sizes. Absent congressional action, we see no authority to set new attachment points that would effectively ban access to the stop-loss insurance needed for these arrangements. Worse, ill-advised changes will not only invite litigation, but will limit access to employer-based coverage and likely increase the uninsured rate.

States regulate the underlying stop-loss insurance as part of the McCarren-Ferguson Act's longstanding statutory framework. And states have taken various steps in regulating the underlying stop-loss insurance plans for small employers around minimum attachment points,

disclosures, and other rules. We do not believe substantive action is necessary and will merely interfere with state regulatory authority.

Small employers work closely with TPAs, stop-loss carriers, brokers, benefits advisors, and other professionals to design their plan's benefits and estimate their expected costs as a plan sponsor. Many level-funded plans provide coverage that is comparable to small group fully-insured or self-insured coverage. Some level-funded plans also comply with state-mandated benefits, even though they are not required to do so.

The plan's third-party administrator and stop-loss carrier use proprietary rating algorithms to set costs. Expected claims costs need to be determined using the specific stop-loss deductible and self-funded plan benefits. Service providers manage funds separately for each plan sponsor. If the full year costs for each plan sponsor's claims are less than the funded amount, a portion of the excess funds are returned to the plan sponsor. Employers and employees share in the cost savings if the plan's design generates savings—for example, by driving utilization to lower-cost or high-quality sites of care. It is the responsibility of the plan sponsor to determine how the refunds are used for the benefit of participants, through taxable refunds, discounts on future premiums, or upgrading plan coverage.

Administrative costs are similar to those found in fully insured plans, covering items such as claims administration, customer service, broker compensation, and network access. Administrative costs will vary based upon the services provided and the expense structures of the third-party administrator and stop-loss carrier.

Section 403 of ERISA requires plan sponsors to establish a trust for plan assets and participant contributions. Under a longstanding Department of Labor (DOL) policy, DOL will not enforce the trust requirement upon participant contributions under certain conditions: (i) the participant contributions are applied only to the payment of premiums for certain fully-insured benefits, (ii) the participant contributions are made under a cafeteria plan, or (iii) benefits are paid solely out of the general assets of the employer (DOL Technical Release 92-01). Any changes to this technical bulletin that would reinstate enforcement of the ERISA section 403 trust requirement for participant contributions and plan assets would impact all self-funded plan sponsors in considerable ways. As the plan is self-funded, in level-funding it is up to the plan sponsor and their tax advisor as to how best to treat any plan funds.

Level-funded group health plans are regulated by several federal agencies including DOL, the Treasury, HHS, and the Equal Employment Opportunity Commission (EEOC). Most self-funded plans are subject to ERISA, which has a set of rules around disclosure, fiduciary controls,

claims and appeal rules, and reporting requirements and failure to comply with these rules can bring potential civil and criminal penalties.

Stop-loss insurance is not medical insurance, but it provides protection against catastrophic or unpredictable financial losses. Therefore, stop-loss insurance falls under state jurisdiction and is also subject to state regulation based on group size and other restrictions. Many states require stop-loss carriers to set an annual aggregate attachment point at a defined percentage of expected claims. In order to come up with a credible estimate of expected claims, stop-loss insurers use risk rules to determine the allowable attachment points available to the group. Groups and their benefit advisors select the stop-loss attachment point that fits their risk tolerance and is within the stop-loss carrier's allowed limits. Aggregate attachment points are determined as the expected claims below the specific attachment point plus additional margin taking into account the self-funded benefit plan provisions. Some states have also implemented stop-loss disclosure requirements to be provided in the sales process to promote additional transparency.

Stop-loss protects the employer by providing maximum liability for a single member or from higher than anticipated overall utilization. Stop-loss does not insure the individual members of the plan.

Agents, brokers, and third-party administrators (TPAs) play an important role in ensuring that small employers understand the components of level-funded plans and know that they must comply with applicable regulations as a plan sponsor, including the risks and benefits of purchasing this type of product and the possible consequences and liabilities related to self-funded arrangements.

Many TPAs offer customer reporting or tools to assist plans with compliance, monitor changes, and communication with plan participants. This includes requirements under the ACA and CAA, such as applicable consumer protections, benefit mandates, Summary of Benefits and Coverage (SBC) requirements, section 6055 and 6056 reporting, prescription drug and healthcare spending reporting, fiduciary and compliance duties under ERISA, and more.

Request for Information on Specified Disease Plans

HBI appreciates the opportunity to offer comments in response to the Departments' request for information (RFI) about specified disease policies. As with hospital indemnity or other fixed indemnity health insurance, HBI believes that specified disease plans are best and most appropriately regulated by state insurance regulators, and we strongly oppose any potential

federal regulatory changes to specified disease plans, particularly any changes that would mirror the proposed rules' changes to hospital indemnity or other fixed indemnity plans. We do not believe that specified disease products would see an increase in interest or purchase as a result of the proposed rules, if they are finalized. Many specified disease policyholders specifically seek out their policies because they have a family history of certain illnesses or because their financial wellbeing could be substantially damaged if they were diagnosed with a covered illness.

Unfortunately, we are not aware of any data sources that provide information and data on specified disease policies, the numbers of policies and certificates in force, characteristics and demographics of policyholders, and common structures (including when benefits are paid and common exclusions/limitations). We are not aware of plan designs that employ or require the use of a network of providers. Additionally, plan structures vary widely; a single carrier may offer policies that pay upon diagnosis but also offer other policies that pay on receipt of treatment for covered illnesses (or other policy variations). This variation is the result of consumer demands in both the individual and group markets, as well as variation among states in their permitted benefit designs.

In the current market, specified disease coverage provides supplemental coverage for diseases that are serious and expensive to treat, such as cancer, heart disease, and strokes. Unfortunately, health insurance doesn't come close to covering the full cost of treating these serious medical conditions. In addition to high deductibles and other cost sharing, treating the condition can involve travel, require additional nonmedical and medical assistance, and other issues. Specified disease coverage provides consumers with additional resources to cover those unplanned expenses. Consumers usually purchase this coverage to protect themselves after seeing someone – often a relative – suffer from one of the named conditions and with an understanding that the consumer purchasing the plan is at higher risk to be diagnosed with the condition.

Specified disease coverage is sold by licensed insurers and through licensed insurance agents. Once issued, specified disease plans continue unless the plan is cancelled by the consumer unless fraud occurs. Specified disease plans are subject to insurance department rate and form review. State insurance departments have specific laws and rules including in some cases limits on the number of diseases that may be covered.

The Department's request for information in the preamble includes specific questions around specified disease coverage, the most important of which is what is the impact on specified disease coverage if the NPRM is adopted as written. In other words, if NPRM upends

consumer access to hospital and fixed indemnity plans, will consumers seek alternative coverage to meet those needs?

We would note that the NAIC will be requiring insurers to file a Market Conduct Annual Statement on "Other Health" products which includes specified disease coverage. This data will be necessary to properly assess specified disease and other products. Any federal action on specified disease coverage would be potentially duplicative and harmful to states' traditional oversight of these plans.

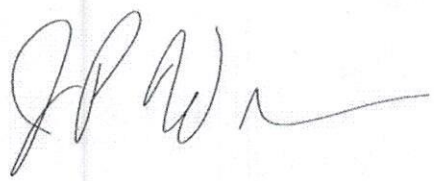
It remains our firm contention that any final rule issued by the Departments should not finalize the proposed hospital and fixed indemnity changes. We are hopeful that lawsuit will be unnecessary, and that any final rule will better protect consumer access to products used to finance the high-cost sharing included in all ACA plans. As a result, we expect to see no impact on the sale of specified disease plans.

Conclusion

HBI appreciates the opportunity to provide input on these proposed rules, which have far-reaching implications for both consumers and the insurance industry. We believe that a collaborative dialogue between all stakeholders is essential for crafting regulations that truly serve the public interest.

We look forward to continuing this important discussion and are committed to contributing constructively to the rulemaking process. Thank you for your attention to these critical issues. Should you have any questions or require further clarification on any of the points raised in our comments, please do not hesitate to contact jpwieske@thehealthbenefitsinstitute.org.

Sincerely,



JP Wieske
Executive Director

NAIC NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS

September 11, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9904-P
P.O. Box 8010
Baltimore, MD 21244-8010

Via Regulations.gov

To Whom it May Concern:

Thank you for the opportunity to comment on the proposed regulations on Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance, published in the Federal Register on July 12, 2023. These comments are submitted on behalf of the members of the National Association of Insurance Commissioners (NAIC), which represents the chief insurance regulators in the 50 states, the District of Columbia, and the United States territories.

As state insurance regulators, we have the primary responsibility for regulating our insurance markets, ensuring consumer protection and market competition. We appreciate the Tri-Departments' attention to the risks of consumer confusion between comprehensive health insurance coverage and more limited plans and arrangements that may not offer the same level of protection against health care expenses. Consumers should be able to understand the coverage they enroll in and should not be misled into choosing a more limited benefit product than they intend to buy. We also acknowledge that due to the underwriting frequently associated with these limited benefit products, some consumers may not have the option to purchase such coverage. At the same time, consumers should have meaningful choices in coverage that are tailored to the markets and consumers in the state. Banning certain plan features at the federal level would limit currently available options for consumers in many states and could lead them to seek coverage in unregulated markets.

Further, federal regulation should not unnecessarily limit state authority to regulate health insurance. We urge the Departments to reconsider the short-term and fixed-indemnity plan limits that would restrict valid state authority in regulating these products. We also strongly urge the Departments to enhance their efforts to cooperate with state regulators to address any allegations of misleading marketing of short-term plans, fixed indemnity products, and level-funded arrangements.

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Short-Term, Limited Duration Insurance

As federal regulation of short-term, limited duration insurance has tightened and loosened over the past several years, the NAIC has consistently commented in favor of states' ability to make their own choices in regulating these products. Because the maximum length of short-term plans is not specified in federal law, we believe it is more appropriate to recognize the role of states as the primary regulators of insurance products and allow states to set their own limits. The states are the more responsive regulator and know better what their individual markets can provide and what their respective consumers need.

Many states have actively considered and chosen to develop their own regulations for short-term, limited duration insurance (STLDI). Some have effectively banned the products or mandate that certain benefits are covered. Several have established time limits of approximately three months, six months, one year, or until the end of the calendar year. Other states have created new regulatory structures that extend important consumer protections and rating rules to STLDI plans. Under these state laws, short-term plans serve consumers who experience gaps in other coverage sources. There is no guarantee that such a gap will last only three or four months. With a federal four-month time limit, consumers in many states will lose plan options currently available to them. Consequently, they will go uncovered or what is worse go without treatment until they can enroll in an approved plan. Allowing for different state choices like these is precisely why the McCarran-Ferguson Act reserves the regulation of insurance for the states.

State regulators strongly request that their flexibility to determine whether, and under what conditions, STLDI is appropriate for their markets and consumers be retained. We request that the proposed rule be revised to continue state flexibility in this area. If the Departments determine that a change to current regulations is necessary, we suggest the Departments adopt either of the following alternative approaches that better protect state choices:

A. Returning the definition of short-term, limited duration insurance to the pre-2016 language, specifically "health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer's consent) that is less than 12 months after the original effective date of the contract."
B. Establishing a federal definition (that could be as limited as the proposed four months), but providing that the definition only applies in the absence of a state promulgating its own definition. This would ensure that states are able to meet the needs of their particular markets while establishing a backstop definition that applies if a state takes no action regarding the definition of STLDI.

While we believe states should retain the authority to define the length of short-term plans, state regulators recognize that some short-term plans are marketed in misleading ways. Some provide inadequate benefits and consumer protections for consumers who expect the benefits of a comprehensive health insurance policy. State regulators have worked individually and through NAIC to address misleading marketing of these plans. In addition to sharing information across states, NAIC has partnered with state attorneys general to enhance enforcement actions. NAIC is also working to

establish greater state authority over lead generators, which are often responsible for the initial contacts that may confuse consumers about the extent of coverage under short-term plans.

We seek greater collaboration with federal officials in our efforts to combat misleading marketing. We appreciate efforts to aid states in reining in improper activity by licensed or registered agents and brokers. But much of the misleading marketing comes from non-licensed entities. We urge the Tri-Departments to work with states as well as the Federal Communications Commission, the Federal Trade Commission, and the Federal Bureau of Investigation to investigate and stop lead generators and sales agents who use deceptive marketing techniques through websites, social media, phone calls, and other means.

NAIC supports strong disclosure language in marketing materials and short-term plan policies. Clear disclosures can help mitigate improper marketing practices, but they are only part of the solution. The updated notice language and additional materials where the NPRM proposes disclosures be required to appear represent improvements. We encourage the Departments to include state-specific language in the disclosures. States should have the option to substitute their own required disclosure language in place of the federally-mandated message. When the federal language is used, it should include contact information for the insurance department in the consumer's state. STLDI marketing materials should also be required to disclose the name of the insurer, the state in which the insurer is domiciled, and the name of any association involved in offering the coverage. This information would be helpful in maintaining accountability and enforcing marketing rules. The disclosure should also note the availability of special enrollment periods for consumers who qualify. Consumers with a qualifying life event should not be misled into thinking the Marketplace is closed to them until the next Open Enrollment Period.

These types of improvements are just a few of the types of processes the states have been reviewing and implementing over the past few years.

Fixed Indemnity Insurance

The NPRM makes a distinction between fixed indemnity benefits paid with respect to an event and those paid "per service," that is, benefits that pay fixed dollar amounts that vary based on the type or level of service a consumer receives. State regulators largely oppose the proposed language that would prohibit "per service" benefits within hospital or other fixed indemnity coverage that qualifies as an excepted benefit policy. Under the Public Health Service Act, the only requirements on this type of coverage to qualify as an "excepted benefit" are: 1) benefits are provided under a separate policy, certificate, or contract of insurance; 2) there is no coordination of benefits; and 3) benefits are paid with "respect to an event." There is nothing in federal statute prohibiting excepted benefits coverage from varying benefit amounts based on the severity of a diagnosis (for example, a heart attack versus a sprained ankle) or treatment site (for example, in an intensive care unit versus an out-patient facility). By adding the additional limitation, the proposed requirement goes beyond the statutory language.

State regulators continue to believe hospital and other fixed indemnity coverage with per service benefits provide important options to consumers to help pay for both health care costs and other expenses. Consumers often use fixed indemnity payments to replace lost earnings, to help pay for non-health related expenses triggered by the need for health services (such as transportation and

lodging), and to cover deductibles, co-pays and other out of pocket expenses. Because both non-health expenses and out of pocket costs can be proportional to the number of health services a consumer requires, "per service" payments are helpful for some consumers. It is clearly in the interest of consumers for fixed indemnity policies to pay more in benefits when, due to the severity of an accident or illness, the consumer incurs more expenses left uncovered by their major medical coverage. Consumers who purchase fixed indemnity products should be fully apprised of the limits of the plan benefits and consumer protections. Again, what fixed indemnity plans can be sold in a state market should be a decision of that state.

State regulators recognize that, like STLDI, some fixed indemnity products are marketed in a misleading manner. We believe the appropriate solution is to enhance collaboration across states and with federal partners to address improper marketing, not for federal regulations to limit plan features that some consumers value. We support the proposed disclosure requirement for marketing, application, and enrollment materials for fixed indemnity products.

State regulators further understand the proposed rules would change the long-standing tax treatment of fixed indemnity policies when premiums are funded on a pre-tax basis. Currently, taxes are imposed only on the portion of fixed indemnity benefits, if any, that exceed an individual's medical expenses. The proposed rules would begin taxing 100% of fixed indemnity benefits as wages. The proposed change is, however, based on the false assertion that fixed indemnity benefits do not provide reimbursement for medical expenses but are rather wage replacement, like disability income coverage. As pointed out above and as the agencies are aware, the health-related events covered by fixed indemnity coverage (for instance, a cancer diagnosis and treatment) give rise to a myriad of medical expenses left uncovered by primary health coverage, including transportation to regional treatment centers, co-payments, and deductibles. It is simply not accurate to characterize benefits used to offset these medical expenses as wages.

Level Funded Arrangements

In the NPRM, the Departments seek comment on level funded arrangements. Some state regulators have concerns about these arrangements, particularly with the understanding among employers and enrollees of the risks such arrangements pose. In cases where the plan's risk is fully transferred to an insurer, so that the insurer can guarantee that the level monthly payments will completely defray all costs of the health benefit plan, the plan is functionally a fully-insured plan and many regulators believe that it should be regulated as such.

In other cases, the "level funded" description is inaccurate and misleading. Employers and enrollees may view level funded arrangements as health insurance that is subject to the consumer protections and risk transfer that characterize insurance. There could be hidden costs that are not fully disclosed. Employers may not recognize the responsibilities they assume when offering a self-funded group health plan or the risk that premiums for the stop loss portion of the arrangement can increase, even retroactively. Level funded plans may be marketed with price comparisons to fully-insured plans that do not disclose material differences between the plans. Both employers and enrollees may be unaware that state and federal consumer protections and required benefits applicable to health insurance do not apply to the arrangements.

Some state regulators believe additional safeguards are needed to better protect against the risks of level-funded arrangements. These regulators support federal action to require disclosures to plan sponsors about federal and state consumer protections that are forfeited by the use of these arrangements in place of health insurance as well as disclosures about potential prospective and retrospective rate increases. We also encourage the Departments to work with states to develop educational and enforcement materials for agents and brokers who sell associated products to improve their disclosures to employers about the details and risks of the arrangements. Educational materials would also be useful for employers regarding their responsibilities as plan sponsors and how level-funded arrangements may trigger them.

Thank you for the opportunity to comment on these important topics. We look forward to continued collaboration with the Departments on health insurance issues.

Sincerely,

Chlora Lindley-Myers
NAIC President
Director
Missouri Department of Commerce and Insurance

Andrew N. Mais *(He/Him/His)*
NAIC President-Elect
Commissioner
Connecticut Insurance Department

Jon Godfread
NAIC Vice President
Commissioner
North Dakota Insurance Department

Scott White
NAIC Secretary-Treasurer
Commissioner
Virginia Insurance Department

https://www.goldwaterinstitute.org/goldwater-to-biden-admin-dont-torpedo-short-term-health-insurance/?utm_source=Goldwater+Master+List&utm_campaign=5fd1abec83-EMAIL_CAMPAIGN_2019_03_31_03_19_COPY_01&utm_medium=email&utm_term=0_31f6bdd0d8-5fd1abec83-248085806&mc_cid=5fd1abec83&mc_eid=bef8c95255

Secretary
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The Honorable Janet Yellen
Secretary
Office of the Secretary
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The Honorable Julie Su
Acting Secretary
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U.S. Department of Labor
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The Departments' proposal would restrict short-term limited-duration insurance (STLDI) contracts to three months (with an option to renew for just one single month) and impose additional restrictions on excepted benefits. The proposed rule is misguided, punishing, ill- timed, and potentially unlawful. This rule would reduce affordable options for families, strip coverage from sick people and leave them facing huge medical bills with no coverage and increase the number of uninsured individuals from anywhere between several hundred thousand people to

millions of people per year. Ultimately, this rule creates clear losers and only speculative and minimal benefits.

The timing of this rule is particularly harmful given that states began redetermining Medicaid eligibility earlier this year, and 18 million people are expected to be removed from Medicaid between April 2023 and the summer of 2024. Several million of these individuals would potentially benefit from STLDI plans.

would be harmed by this proposed rule. The main beneficiaries would be health insurance companies that want to restrict alternative options, forcing Americans to buy heavily government-subsidized products (government subsidies cover roughly 80 percent of the premium for the average exchange enrollee) from them and not their unsubsidized competitors.

From a legal perspective, this rule radically changes the definitions of short-term and limited duration, interpreting them out of context, contrary to history, and in a manner not foreseen by Congress. For all but one and one-half of the past 26 years, federal rules permitted the STLDI contract period to be up to 364 days. Moreover, regulators reversed the condensed period before it could be challenged in court.

In the regulatory impact analysis of the Departments' 2018 rule that restored the long- standing contract period for STLDI to up to 364 days, the Departments wrote of their belief that "the need for coverage options that are more affordable than individual health insurance coverage is critical, combined with the general need for more coverage options and choice. Therefore, the Departments believe that the benefits associated with this rule outweigh the costs."1 The current proposed rule does not even attempt to meaningfully quantify how the benefits of a shorter time frame exceed the costs.

The main supposed benefit is to reduce consumer confusion between STLDI and Affordable Care Act (ACA) coverage. In doing so, the Departments violate the Office of Management and Budget's description of "good regulatory analysis" in Circular A-4.2 According to A-4, "the possibility of poor information processing is not enough to justify regulation.... In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the

need for ... mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards of disclosing information of the hazard to buyers or user." Rather than restricting the short- term plan contract to only a few months—which would remove more flexible insurance options, strip coverage from the sick, and increase the number of uninsured Americans— the Departments should consider alternatives to meet their objectives in less harmful ways. One such alternative is increased plain-language disclosure from plans on what is and is not covered by the insurance. Another alternative is to ensure that short-term plan contracts can last through the end of the calendar year so people would not have gaps in their coverage.

The proposed rule does not come close to "reasoned analysis" for drastically modifying a previous regulation. The costs of reduced coverage options and forcing people to go without coverage are substantial versus the nearly indiscernible and speculative benefits from the proposed restrictions. And the proposal's analysis ignores the actual data that shows that STLDI favorable states have had much better performance in their ACA individual market in terms of enrollment, insurer participation, and premiums than states that restrict or prohibit STLDI.3 According to an analysis from Paragon Health Institute's Brian Blase, "Between 2018 and 2023: 1) Exchange enrollment was up 62.7 percent in STLDI favorable states, more than 13 times greater than the 4.7 percent increase in STLDI unfavorable states; 2) The number of insurers selling exchange plans in STLDI favorable states increased 105 percent, more than three times the 32 percent increase in STLDI unfavorable states; and 3) Exchange plan premiums, particularly for benchmark plans and gold plans, decreased much more significantly in STLDI favorable states."

Because of the profound harm that would result from this rule, and because there are better ways to improve consumer understanding without restricting insurance options, we urge you to withdraw the proposed rule.

The proposal violates Americans right to control their health care and violates President Biden's promise

Americans have the right to spend their own money on the health care and coverage that they prefer. Millions of Americans decide each year that STLDI plans are the best option for them. On January 27, 2010, then-Vice President Biden applauded when then-President Obama told Congress it is a "right of Americans who have insurance to keep ... their plan."5 Moreover, when running for president on July 16, 2020, Biden pledged to uphold that right, and that if he became president, "If you have private insurance, you can keep it."6 Thus, by taking this action, the Departments would violate these pledges by forcing insurers to cancel STLDI plans after just four months.

The proposal will strip coverage from sick people, leaving them vulnerable to expensive medical bills

Federal rules currently permit people to purchase STLDI with a contract period of 364 days that can be renewed for up to three years. States have the authority to alter STLDI rules, but in about half of states, people are able to buy STLDI products that last up to three years. The Departments' proposal would limit the contract to three months and permit a renewal for just a month throughout the country. This will mean that a person who gets sick during the coverage period will lose insurance protection when that coverage period ends. The National Association for Insurance Commissioners raised this same concern in a letter opposing the Departments' proposed rule in 2016 to reduce the contract period to three months:

In conclusion, there are instances when consumers simply cannot afford, even with the subsidies, an insurance plan with minimum essential coverage (MEC) or may have other reasons for choosing a shorter-term plan. Their options should not be limited to either paying for coverage they cannot afford or exposing themselves to the risk of losing their coverage after three months if they become sick. We oppose this new definition of short- term, limited-duration insurance because it could harm some consumers, limit consumer options, and have little positive impact on the risk pools in the long run.

For example, assume an enrollee who purchases a STLDI plan in January is diagnosed with cancer in February. That individual will lose his plan in April and will not have any health insurance plan in which to enroll until

the following January as a result of the ACA open enrollment, which limits when people can buy health insurance. In those intervening eight months, the enrollee will either be on the hook for massive medical bills or choose to forgo care. Thus, this proposal, if finalized, would harm the individual's health and financial well- being by stripping coverage from people when they most need it.

If finalized this rule would create a set of victims just like the 2016 Obama rule did. For example, in 2017, Jeanne Balvin was left with almost $100,000 in medical bills because she reached the end of her short-term plan contract period (because of the 2016 rule) and could not get other coverage.

The proposal will significantly increase the number of uninsured

The main goal of the ACA was to increase health insurance coverage, and the law preserved the long-standing exemption from federal health insurance regulation that Congress created for STLDI. In other words, the ACA left the federal rules around STLDI, which permitted contracts of up to 364 days, untouched. The Departments' proposal thus cuts against the purposes of the ACA by both restricting a coverage option that Congress did not and increasing the number of the uninsured.

Since this rule largely reverses the 2018 rule that allowed for enhanced STLDI policies, the estimated effects will likely be the reverse of what was projected under that rule. According to the average of the projections from the Centers for Medicare and Medicaid Services Office of the Actuary, the Congressional Budget Office, the Center for Health Economy, the Urban Institute, and the Commonwealth Fund of the 2018 rule, the Departments' current proposal will likely increase the number of the uninsured by about 1.8 million people. Many of the newly uninsured will likely be people who purchased plans for three months but then were unable to select new plans after the coverage periods ended.

STLDI offers better coverage than ACA plans for many people

One rationale offered by the Departments for restricting the STLDI contract period is that ACA plans offer high-quality comprehensive coverage and STLDI do not. The Departments err in their assumption here. For many people, the quality and comprehensiveness of STLDI is better than for ACA plans.

A 2019 study by health policy expert Chris Pope of the Manhattan Institute found: "For equivalent insurance protection, the premiums for STLDI plans are lower than—in some cases, almost half the cost of—premiums on the exchanges."10 The non-partisan U.S. Congressional Budget Office reports that STLDI often "have lower deductibles or wider provider networks than plans in the fully regulated nongroup market" at premiums "as much as 60 percent lower than premiums for the lowest-cost bronze plan."11 Pope's review found that STLDI plans that cover all the ACA's essential health benefits are widely available, with the sole exception of maternity services.

Short-term plans typically have much broader networks than ACA individual market plans do. Hospitals and doctors are more likely to participate in short-term plans because they tend to offer better payment rates than ACA plans do. For example, short-term plans in Texas typically cover the renowned MD Anderson Cancer Center, but not a single ACA plan does. Consumers who prefer networks broader than the ACA offers should have that option. Restricting the utility of short-term plans by reducing the permissible contract length harms those who value greater choice of providers in their health plans.

The proposal will lead to higher premiums and higher federal subsidies

The rule would cancel STLDI coverage that people have purchased with their own money. Many would remain uninsured, particularly if they do not qualify for large subsidies. Some individuals who would have purchased STLDI in the absence of this rule would choose to purchase ACA coverage instead, where they would face substantially higher premiums, narrower networks and higher cost-sharing.

Some of these individuals would likely qualify for a premium tax credit to cover a portion of the ACA premiums, raising the costs of this rule to taxpayers for people who switch from STLDI to a subsidized exchange plan. In 2022, 78.3 percent of premiums collected by insurers for their exchange plans came not from the people enrolled in their policies but from the federal government. The rule would thus cancel coverage that costs taxpayers nothing and prioritize coverage for which taxpayers would bear the vast majority of the cost.

Many people are unemployed for longer than three or four months

People who are unemployed can purchase STLDI to insure them between jobs, which could include a waiting period for coverage offered through a new job. STLDI is much less expensive than COBRA and unsubsidized ACA plans, and thus are an attractive source of coverage for many of the unemployed. Many people who are unemployed will face more than a three- or four-month health insurance gap period. According to data from the Federal Reserve, the average amount of time that people were unemployed was 20.7 weeks in June 2023. And during poor economic conditions, this average time is much higher. In July 2011, the average number of weeks that the unemployed were without work was 40.7 weeks, or more than nine months. Since one of the primary groups that benefit from STLDI are workers between jobs and since the average amount of unemployment exceeds four months in good economic times, and exceeded nine months at one point last decade, a three or four month limit on STLDI will leave more unemployed people with gaps in their coverage.

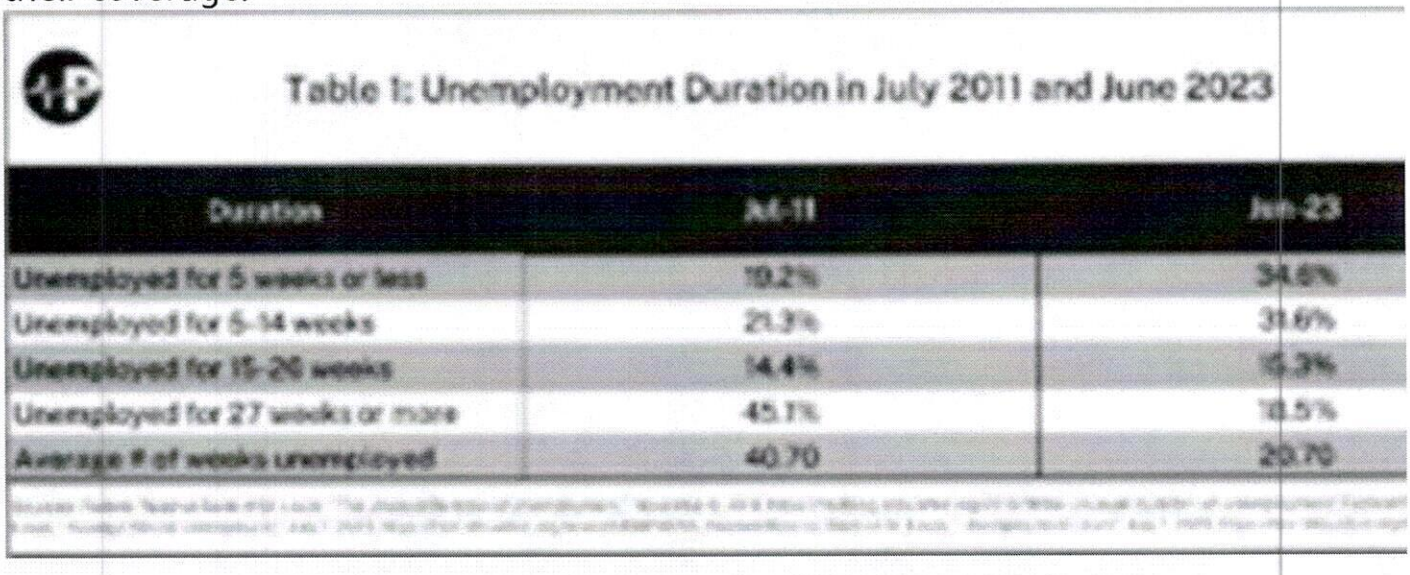

Table 1: Unemployment Duration in July 2011 and June 2023

Duration	Jul-11	Jun-23
Unemployed for 5 weeks or less	19.2%	34.6%
Unemployed for 5-14 weeks	21.3%	31.6%
Unemployed for 15-26 weeks	14.4%	15.3%
Unemployed for 27 weeks or more	45.1%	18.5%
Average # of weeks unemployed	40.70	20.70

Most states choose longer contract periods for STLDI

While the federal government can regulate only the allowable contract period, states can place additional requirements on STLDI and even restrict insurers' ability to underwrite STLDI. The fact that most states permit STLDI for longer than what is proposed in the federal rule is a

strong indication of the misguided nature of the federal rule.14 Most states fully permit STLDI consistent with the 2018 rule, an indication that there is broad acceptance among most states of the 364-day and three-year time periods contained in the current rules.

This proposal is unlikely to help and will potentially harm the ACA individual market

In a 2021 Galen Institute study, Brian Blase assessed the trends in the ACA exchanges— enrollment, premiums, and insurer participation— between states that restricted STLDI and states that fully permitted them consistent with the 2018 rule.15 He found more favorable trends from 2018 to 2020 in the individual market in each of the three measures in states that fully permitted STLDI. Thus, there was no evidence from the first few years of the enhanced contract period for STLDI of any adverse effect on the ACA market.

Blase updated this analysis using 2021-2023 data. As discussed above, the subsequent data shows that these trends continued through 2023. The takeaway: State individual markets had much more favorable trends in states that fully permitted STLDI.

Based on the data, it appears possible that the 2018 rule enhancing STLDI actually strengthened the ACA market by providing sick people with an alternative source of coverage and promoting insurer competition in the overall market. Enhanced competition benefits consumers, resulting in greater choice of plans and lower premiums.

Importantly, the analysis of the actual data is far superior to a 2022 analysis released by the Commonwealth Fund and cited by the proposed rule that relied on risk scores and not actual insurer participation and premium data.16 In fact, replicating the Commonwealth Fund's analysis using additional years of data shows that their result disappears and that the ACA markets, including off-exchange enrollment, improved in STLDI favorable states relative to STLDI unfavorable states.

STLDI is an important option in the modern economy

The proposed rule will increase providers' uncompensated care The public comments received by the Departments thus far mention specific groups that benefit from STLDI and are harmed by this rule, including traveling nurses and truckers.18 Many people now are contract workers

who are not offered health coverage through the workplace. STLDI plans are a flexible, affordable option for a modern workforce, including the self-employed and small business owners. One of the purposes of the ACA was to reduce the amount of uncompensated care provided by hospitals and doctors. By increasing the number of the uninsured, this proposed rule would increase the amount of uncompensated care, including by undocumented immigrants—one of the main populations who benefit from the availability of STLDI.

The proposed rule usurps state authority to regulate STLDI

In creating STLDI and excepted benefit health plans, Congress shielded various insurance products from federal insurance regulation. This statutory provision left the regulation of such plans to the states. The Biden administration has found no evidence that states are failing to adequately regulate STLDI. On the contrary, states have taken multiple approaches, including some that restrict the duration and renewability of these policies and some that limit plans' underwriting ability.19 By proposing to change the definition of STLDI, the administration is attempting to preempt state authority, not in accordance with statutory law, but through unilateral, discretionary changes in regulation. Congress has shielded STLDI and certain other categories of excepted plan from federal regulation, leaving their oversight to state legislatures and insurance commissioners. This also reduces the amount of learning that occurs through competitive variation in state regulatory approaches.

Regulatory impact analysis contained in the proposed rule is inadequate for the public to comment

The proposed rule's regulatory impact analysis (RIA) does not quantify any benefits, although it does quantify the number of people joining exchanges (60,000 after 2025), the effect on unsubsidized ACA premiums (-0.5%) and government savings from that ($120 million annually after 2025). There is no projected effect in 2024 and 2025 because of the continued effects of the expanded ACA subsidies. These expanded subsidies have already been extended once and are unlikely to expire after 2025. Yet the RIA makes no mention of this, and does not contain any analysis of how the STLDI restrictions would interact with the

expanded subsidies to affect enrollment, premiums, and subsidies after 2025.

According to the Departments' analysis, the 60,000 people from CBO's projections are currently purchasing in the exchanges only because of the extended ACA subsidies. Without those expanded subsidies, CBO projects that they would purchase STLDI plans instead. After 2025, the expanded subsidies expire. Because this rule takes away the STLDI option for them, they would be forced to buy exchange plans. Ironically, the Departments' proposed rule makes these people worse off, forcing them into costly plans that they purchase only because the government took away the more attractive alternative.

The RIA also does not quantify the harm to those losing their STLDI coverage, which would greatly exceed $120 million.

The RIA quantifies exactly one cost of the proposed rule, which—ludicrously—is the time it takes for 250 market participants to read the rule. Their time is worth $76.20 per hour and each will need four hours of reading time. The Departments welcomed comments on this approach to estimating the cost for interested parties to read and interpret these rules. The Departments obsess over trivial reading costs while completely ignoring opportunity costs and the plight of people who are no longer able to spend their own money on the coverage insurance coverage. The failure to do a reasonable RIA runs afoul of the Administrative Procedures Act.

Main supporters of this proposal would financially benefit from it

The main supporters of this rule are big insurers that participate in the ACA and want to eliminate their competition and increase their profits. The Association for Community Affiliated Plans (ACAP) sued the 2018 Trump rule under competitor standing. According to the Cato Institute's health studies director Michael Cannon:

Complaining that STLDI plans were cutting into their business, ACAP asked federal courts to remedy that "injury" by reinstating this heartless [Obama] rule.

To be clear: ACAP is asking federal courts to improve its members' bottom lines by stripping coverage from their competitors' enrollees after three months, because doing so will frighten consumers into

enrolling in ACAP members' plans. ACA plans must not be very attractive if the insurers who sell them feel they cannot compete unless the government actively punishes people who choose their competitors' plans.20

The proposed rule would increase administrative costs

According to the Departments' analysis, STLDI has a lower medical loss ratio (MLR) than individual market plans do. However, one of the main reasons for this is because of the shorter contract period. In essence, insurance involves a fairly fixed amount of administrative costs, and those costs will be a larger share of the total premium if the contract period is shorter. Ironically, the Departments' proposed rule would likely decrease MLRs for short-term plans by reducing the permissible contract period.

One Alternative

A consequence of this proposed rule, if finalized, would be taking coverage from the sick and increasing the number of people without health insurance. One way to reduce the harm would be to allow uninsured individuals at the conclusion of the ACA open enrollment period to purchase STLDI plans that last until the next year, when they would be eligible for coverage.

Conclusion

Americans are not well-served when government prohibits the sale of insurance products. There has not been a public outcry about the problems with STLDI. If anything, the public comments on the proposed rule are largely from middle-class individuals and families who will be harmed by the rule as well as from health insurance brokers who are concerned that the rule would make it overly difficult for many individuals and families to find affordable coverage. For more than 10 months out of the year, people cannot buy ACA plans, and coverage for those who enroll during that open season does not take effect until January. STLDI, on the other hand, can be bought at any point in time, with the coverage often beginning immediately. Given the modern workforce and the large number of people being removed from Medicaid, restricting STLDI plans inflicts untold harm, particularly on the sick, without any benefit. It would

worsen Americans' health and financial well-being. As such, we strongly urge you to withdraw this rule.

Sincerely,

Brian Blase, Paragon Health Institute
Theo Merkel, Paragon Health Institute
Casey Mulligan, University of Chicago
Doug Badger, Paragon Health Institute
Tom Miller, American Enterprise Institute
Chris Pope
Grace-Marie Turner, Galen Institute
Joe Grogan, USC Schaeffer
Tomas Philipson, University of Chicago
Tarren Bragdon, Foundation for Government Accountability
Hayden Dublois, Foundation for Government Accountability
Avik Roy, The Foundation for Research on Equal Opportunity
Paul Winfree, Economic Policy Innovation Center
Stephen Parente, University of Minnesota
Dean Clancy, Americans for Prosperity
Joel Zinberg, Competitive Enterprise Institute and Paragon Health Institute
Heidi Overton, America First Policy Institute
Josh Archambault, State Policy Network
Sally Pipes, Pacific Research Institute
Kansas State Senator Beverly Gossage
John C. Goodman, Goodman Institute for Public Policy Research
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Lindsay Killen, The James Madison Institute
Hadley Heath Manning, Independent Women's Forum
Andrew Langer, Director of the CPAC Foundation Center for Regulatory

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Affiliations listed for identification purposes only.

American Assoc.
of Ancillary Benefits

September 11, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9904-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted *via* www.regulations.gov

Re: CMS-9904-P, Proposed Rules: Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance

Dear Administrator Brooks-LaSure:

We appreciate the opportunity to comment on the proposed rules concerning Short-Term, Limited-Duration Insurance; Independent, Noncoordinated Excepted Benefits Coverage; Level-Funded Plan Arrangements; and Tax Treatment of Certain Accident and Health Insurance (the "Proposed Rule").[1]

The American Association of Ancillary Benefits ("AAAB") is a non-profit, trade association that supports and advocates for the ancillary benefits industry on behalf of carriers, vendors, third parties, and distributors. We also advocate for specialty carriers, prepaid legal services, and our members also include advertisers and brokers that interact with Medicare beneficiaries every year.

Our comments concern a few specific provisions contained in the Proposed Rule: 1) The 4-Month STLDI Definition, and 2) Per-Period Exclusivity for Fixed Indemnity Plans.

As explained in greater detail below, the Proposed Rule cannot withstand scrutiny as a legal matter and would harm individuals and their families seeking context-appropriate health insurance and supplemental health insurance, and bankrupt value-adding industry participants. For these reasons

[1] 88 Fed. Reg. 44,596 (July 12, 2023) (hereinafter, the "Proposed Rule"). For simplicity, this comment letter will hereinafter refer to the various agencies contributing to CMS-9904-P, inclusive of the Centers for Medicare & Medicaid Services, as "the Departments."

and others, we urge the Departments to withdraw the proposed changes to STLDI and Fixed Indemnity insurance and reject any similar temptations to modify statutory language affecting Specified Disease coverage.

A. THE 4-MONTH STLDI DEFINITION.

The Proposed Rule would create an entirely new and extra-statutory definition of "short-term, limited-duration insurance" ("STLDI") by amending existing regulations at 26 C.F.R. § 54-9801-2, 29 C.F.R. § 2590-701-2, and 45 C.F.R. § 144.103.[2] We strongly urge the Departments to reconsider carefully. By cleaving one statutory phrase into two, the Departments will trespass unlawfully into a role reserved for Congress and Congress alone. In so doing, the Departments propose to subdivide the phrase into two, separate definitional parts, each accompanied with discrete periods of time. First, "short-term" will mean "a policy, certificate, or contract of insurance with an issuer that has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance.[3] Second, "limited-duration" will mean "a maximum coverage period that is no longer than 4 months in total, taking into account any renewals or extensions."[4] These new, extra-statutory requirements will apply to individual coverage periods beginning on or after 75 days after the date of the final rule's publication date.

Defining STLDI plans in this way as limited to three months (plus a one-month renewal period) is unlawful. If issued in its current form, the Proposed Rule "would not impose requirements on STLDI," but "[r]ather, they would define STLDI" to mean three months, with a one-month renewal period.[5] The Departments lack authority to implement this limitation for at least six separate reasons: (1) The Departments' acknowledged lack of relevant business data necessary to perform an adequate and requisite cost-benefit analysis concerning the 4-Month STLDI Definition under the Regulatory Flexibility Act ("RFA") precludes the Departments from finalizing the Proposed Rule in its current form; (2) The authorizing statute set forth in section 2791(b)(5) of the 1996 Public Health Services Act (the "PHS Act") does not grant the Departments authority to "define" statutory terms that are unreasonable; (3) The proposal to invent not one, but two, new, separate definitions, each of which apply a three- and one-month maximum period of time within a given coverage year, is a wholesale substitution for Congressional action; (4) The consumer protection reasons the Departments cite to justify the Proposed Rule are unsupported by substantial evidence; (5) This manner of insurance regulation that is ultimately directed at consumers, not insurers, is a matter of state law, not federal law; and (6) Inventing time-limitations purportedly derived from one statute in order to serve the political interests contemplated under a separate statute enacted decades later is unreasonable and an abuse of discretion.

1. <u>The Departments' acknowledged lack of relevant business data necessary to perform an adequate and requisite cost-benefit analysis concerning the 4-Month STLDI Definition</u>

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[2] Proposed Rule at 44,611 (col. a).

[3] *Id.* at 44,596 (col. a-b).

[4] *Id.* at 44,611 (col. b).

[5] *Id.* at 44,649 (col. a), 44,611 (col. a).

under the Regulatory Flexibility Act ("RFA") precludes the Departments from finalizing the Proposed Rule in its current form.

The RFA requires federal agencies to initially assess the effects of their regulations on small businesses and other small entities.[6] A federal agency can only complete these RFA obligations in a proposed rule triggering RFA requirements by including "a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.[7] The Departments acknowledge they cannot prepare that initial analysis:

> [D]ue to a lack of data, the Departments are unable to precisely estimate how many agents and brokers might be affected by these proposed rules and the magnitude of the potential changes in compensation. The Departments seek information on the number of agents and brokers who sell STLDI, fixed indemnity excepted benefits coverage, and individual health insurance coverage, respectively, and how their compensation might be affected by these proposed rules, if finalized.[8]

There can be no dispute that the Proposed Rule is soliciting required, quantitative information concerning the number of agents and brokers whose compensation will be affected by the Proposed Rule, not performing a requisite RFA initial analysis. Once that data is available, we urge the Departments to commit to that rigorous analysis. Until such time, however, the Departments cannot satisfy rulemaking requirements necessary to finalize the Proposed Rule in its current form.[9]

2. The authorizing statute set forth in section 2791(b)(5) of the 1996 Public Health Services Act (the "PHS Act") does not grant the Departments authority to "define" statutory terms that are unreasonable.

The Departments lack authority to implement their 4-Month STLDI Definition within a given coverage year contemplated under section 2791(b)(5) of the PHS Act. This statutory provision provides "[t]he term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, *but does not include short-term, limited-duration insurance*." (Emphasis additional.) The meaning of this express statutory definition—which Congress directed decades prior—is clear: "Short-term, limited-duration insurance" is not individual health insurance coverage. Where the text is as clear as it is here, "that is the end of the matter."[10]

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[6] 5 U.S.C. §§ 601-612, 603(a).

[7] 5 U.S.C. § 603(b)(3).

[8] *Id.* at 44,648 (col. a).

[9] *See* 5 U.S.C. § 553.

[10] *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984) ("*Chevron*").

In 1997, the agency interpreted this phrase in rules implementing certain requirements under the 1996 Health Insurance Portability and Accountability Act ("HIPAA").[11] Bounded by the fact that section 2791(b)(5) of the PHS Act states that "short-term, limited-duration insurance," is not individual health insurance coverage, and informed by the fact that contracts for individual health insurance coverage are typically set forth on an annual basis, the agency interpreted STLDI to mean "less than 12 months after the original effective date of the contract."[12] This interpretation was not only logical, but also satisfied normal standards of statutory construction, and likewise conformed with existing state regulations governing STLDI.[13] That remains true to the present time.

That also remains true despite various efforts to modify this definition. In 2016, the Departments revised the definition of STLDI to cover only plans that expired "less than 3 months after the original effective date of the contract" and also prohibited renewals.[14] The Trump administration effectively returned the definition of STLDI to less than 12 months, and in 2018, extended the renewal term *beyond* 12 months and up to a total of 36 months.[15] That extension did not go unchallenged in *Association for Community Affiliated Plans v. U.S. Department of Treasury*, 966 F.3d 782 (D.C. Cir. 2020) ("*ACAP*").

Evidently, STLDI has become a political football. But this should give the Departments no license to overstep statutory authority, abandon regulatory certainty, or harm consumer choice. Indeed, the Departments have now effectively switched sides and adopted the position of the challengers in *ACAP* (who unsuccessfully argued to restrict the definition of STLDI to three-months and without a renewal term), while abandoning their earlier position as defendants (who successfully argued that they had wide discretion to expand the definition of STLDI). Today, the Departments will most likely argue their wide discretion permits a dramatic restriction of STLDI to three-months and one month of renewal. These political machinations aside, the *ACAP* decision at least makes clear that to the extent the Departments may exercise policymaking authority, they must do so "reasonably."[16]

The Proposed Rule is decidedly unreasonable. The regulations proposed will dramatically curtail the availability of STLDI from up to 36 months, to a maximum of 4 months—a 32 month cut—and will carry disastrous consequences for consumers and plans alike. The entirely untested 4-Month STLDI Definition (three-months plus one month of renewal) will create unstable market

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[11] Pub. L. No. 104-191, § 102(a), 110 Stat. 1936, 1973 (codified at 42 U.S.C. § 300gg-91(b)(5)).

[12] *See* 62 Fed. Reg. 16,894, 16,928, 16,942, 16,958 (April 8, 1997).

[13] *See* 42 U.S.C. § 300gg-92.

[14] *See* Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited Duration Insurance, 81 Fed. Reg. 75,316, 73,326 (Oct. 31, 2016).

[15] *See* 83 Fed Reg. 38,212 (Aug. 3, 2018).

[16] *Ass'n for Cmty. Affiliated Plans v. U.S. Dep't. of Treasury*, 966 F.3d 782, 794 (D.C. Cir. 2020) ("*ACAP*") ("But as judges, our role is narrow: to ensure only that the Departments reasonably exercised the policymaking authority granted to them and not to us.").

conditions and harm consumers who rely on the valuable protections STLDI provides and has provided for decades.

Equally unreasonable is the Departments' proposal to effectuate these new, extra-statutory limitations within 75-days of publication of the final rule. Imposing such a limited timeframe to comply with profound, market-disrupting changes amounts to a clear abuse of discretion, and the Departments should reject such an approach that enhances the level of certain harm that will occur from implementing these extra-statutory regulations, regardless of the timeline proposed. As the authorizing statute states clearly, STLDI is not individual health insurance coverage, and in conformity with HIPAA requirements, may reasonably mean "less than 12 months after the effective date of the contract."

3. The proposal to invent not one, but two, new, separate definitions, each of which apply a three- and one-month maximum period of time within a given coverage year, is a wholesale substitution for Congressional action.

The Proposed Rule appears to suggest that because "[t]he PHS Act does not [] define the phrase "short-term, limited-duration insurance,"[17] the Departments should do what Congress did not by subdividing this explicit statutory phrase into new and separate definitions for both "short-term" *and* "limited-duration."[18] No so. The "Secretary may not rewrite the statute."[19] The Departments' effort to partition statutory language, then assign each partition a specific quantity of months, is a bold rewriting of the statute.

Congress meant what it wrote, and Congress knows how to impose time limits where necessary.[20] Read in context, "short-term, limited-duration insurance" is simply a form of insurance coverage that does not span the full coverage year in the individual market.[21] This could mean 11 months, 10 months, 8 months and four days, 6 months and 23 hours, or some other period an individual elects to purchase that is shorter in term than the standard one-year term and duration of a plan coverage year in the individual insurance market. If the Departments are frustrated by the fact that "short-term, limited duration insurance" is "outside the scope of federal authority to regulate,"[22] they should direct their frustration to Congress. Congress may amend its own language. Agencies may not. *See Jordan*, 194 F.3d at 171-72 (an agency's decision to "add an obligation that is not in the statute . . . changed the nature of the statute").

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[17] Proposed Rule at 44,596, 44598 (col. c)

[18] *Id.* at 44,611 (col. a).

[19] *See Jordan v. Sec'y of Educ.*, 194 F.3d 169, 171–72 (D.C. Cir. 1999) ("*Jordan*") (the "Secretary may not rewrite the statute").

[20] *ACAP*, 966 F.3d 782, 794 ("Congress knows how to impose time limits—after all, it defined 'short coverage gaps' as 'less than 3 months—but it didn't do so for STLDI plans.").

[21] *Id.*

[22] Proposed Rule at 44,638 (col. b).

In addition, the Departments' proposal to apply this new definition of "limited-duration" as a basis for prohibiting the renewal or extension of an STLDI policy, contract, or certificate of insurance sold to the same policyholder by the same issuer beyond a one-month period is also improper. The Departments' concerns regarding "stacking" policies in this fashion are not solved by concocting an extra-statutory definition of "limited-duration." As the *ACAP* decision explained, "[o]ne of HIPAA's central reforms was to guarantee renewability of most "individual health insurance coverage [citation omitted]. Of course, STLDI plans are exempt from that guarantee because they are exempt from HIPAA's definition of "individual health insurance coverage." *ACAP* at 12. But the Departments cite no statutory authority that prevents insurers from renewing expired STLDI policies, and there can be no dispute that from 1997 to 2016, renewals were allowed with the insurer's consent. This attempt to create a limitation where none exists in the statute is unlawful.

4. The consumer protection reasons the Departments cite to justify the Proposed Rule are unsupported by substantial evidence.

The Departments rely on various, vague, or otherwise speculative and anecdotal "consumer protection" concerns supporting the effort to deprive consumers of the opportunity to renew their STLDI plans. These concerns are misplaced and distract the public from the fact that the Departments lack statutory authority to prevent consumers from "stacking" STLDI plans as Congress intended. Nothing in the plain language of section 2791(b)(5) of the PHS Act prevents a consumer from "string[-ing] together" multiple, consecutive STLDI policies within a coverage year, as that consumer may deem fit for herself or her family members.[23] Yet the Departments express their disdain for consumer choice by leveling various concerns that the original statute itself did not and does not contemplate, and more importantly, did not authorize for further rulemaking.

For example, the Departments contend that stacking multiple STLDI policies could be effectuated in such a manner as to "look similar to the annual renewals that are common for comprehensive coverage but without the benefits the consumer would receive from comprehensive coverage."[24] That would make sense if STLDI policies did not already require the currently mandated Federal consumer protection notice attached to the first page of each STLDI policy sold in this country, let alone the new requirements for the consumer protection notice (and marketing materials for) proposed in this rule.[25] Demonstrably, the Proposed Rule overlooks the fact that it can solve at least this logical problem within the same preamble text without resorting to extra-statutory action.

Nor do the Departments resuscitate the fatal defects in this extra-statutory rulemaking by "reflect[ing] on instances when individuals may experience a temporary gap in coverage," or pointing to provisions of the PHS Act regulating *group* health insurance.[26] Instead, the Departments should "reflect" more before finalizing these ill-conceived regulations, starting with their limited statutory authority, and then expanding their "reflections" to the devastating impact the Proposed Rule will have on consumer choice. The Departments fail to "reflect" upon the

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[23] *Id.* at 44,612 (col. a).

[24] *Id.* at 44,612 (col. b)

[25] *See, e.g.*, *id.* at 44,614 (col. c)-44,615.

[26] *Id.* at 44,610 (col. c).

significance or effectiveness of the currently mandated Federal consumer protection notice attached to the first page of each STLDI policy sold in this country. Rather, the Departments simply speculate that because an undefined number of consumers may *still* remain vulnerable to certain misleading or deceptive marketing tactics, *all* consumers are therefore categorically incapable of intentionally selecting an appropriate STLDI plan within a coverage year, even if the consumer deems fit.[27]

Similarly, the Departments fail to "reflect" on the fact that STLDI has never been a product consumers utilized to cover pre-existing conditions, and yet the Departments nevertheless speculate that because some consumers may misunderstand pre-existing condition provisions of a contract (or even COVID-19 coverage options), they are categorically incapable of intentionally selecting an appropriate and affordable STLDI plan within a coverage year, if the consumer deems fit.

Without the benefit of more robust data, additional input, and perhaps more "reflection," the 4-Month STLDI Definition amounts to a solution in search of a problem. Accordingly, we urge the Departments to withdraw the proposed 4-Month STLDI Definition because they have provided no evidence demonstrating that the 4-Month STLDI Definition would effectively address their stated concerns.

Finally, the Departments have proposed that the 4-Month STLDI Definition would effectively address certain perceived concerns about unscrupulous or misleading marketing tactics. However, the Departments fail to cite any evidence demonstrating that consumers are incapable of performing their own due-diligence and research, freely exercising their own judgment, or purchasing STLDI for themselves or their families according to their own needs, nor that state regulatory authorities – who have primary regulatory over producer marketing and conduct – have been ineffective in overseeing the markets they are charged with regulating.

Whether the Departments' political objectives are noble or not is immaterial—the Departments' effort to *replace and re-write* Congress's words with their own preferred choice or arrangement of words does great violence to the principles of separating power in American government. Accordingly, setting aside the negative impact to consumer choice and options, this proposal to "define" or even redefine the statutory construct of STLDI by quantifying a specific number of months within a given coverage year, or to prevent so-called "stacking" – whether within the same carrier or group of controlled carriers – fails as a matter of law.

5. <u>This manner of insurance regulation that is ultimately directed at consumers, not insurers, is a matter of state law, not federal law.</u>

Masquerading in the service of meeting political objectives for the ACA, the Proposed Rule also flouts individual state rights to regulate insurance independently, without any meaningful analysis of existing and/or conflicting constitutional and/or state laws or regulations.[28] The agency's

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[27] *See, e.g., id.* at 44,607 (col. c)

[28] *See, e.g.*, U.S. Const., Art. I § 8, cl. 3 (the "Commerce Clause"); The McCarran-Ferguson Act of 1945, 15 U.S.C. § 1101-1105 *et seq.*, *United States v. South-Eastern Underwriters Ass'n*, 322 U.S. 533 (1944); The Sherman Antitrust Act of 1890, 15 U.S.C. §§ 1-7.

misleading characterization of its "Federalism" analysis amounts to mere lip service because it relies on the false premise that the new definition of STLDI in the Proposed Rule is proper.[29] It is not. The proposal to re-define STLDI will have a profound and significant effect on the *business* of health insurance taking place in individual state insurance markets, which is ultimately consumer-driven, and therefore concern matters under state law.

Somewhat counterintuitively, the Departments note that individual states already have the discretion to regulate STLDI plans on their own, and already do so under a panoply of regulations that are tailored to individual circumstances and needs.[30] Yet the Departments offer no explanation why it should engage in a self-aggrandizing federal rulemaking if the qualitative features of STLDI are already being effectively regulated at the state level. Nothing in the Proposed Rule indicates why individual states should be deprived the opportunity to regulate STLDI plans within the scope of their own authority and as they have done for decades even prior to the enactment of HIPAA, or why the Departments have license to intrude upon on existing state statutes and regulations concerning STLDI that is not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage[31].

The simple and uncontroverted fact remains that the underlying statute here was not intended to regulate consumers, but rather, insurance plans. Using a 4-Month STLDI Definition (or more specifically, a one-month definition of "limited-duration") is clever but remains transparent nevertheless.[32]

Moreover, while we share the Departments' concerns about fraudulent, deceptive, or otherwise misleading marketing efforts, these concerns are not solved by through unlawful agency rulemaking. Instead, the Departments should focus their attention on ways to enforce existing legal authorities, both state and federal, to combat illegal marketing schemes, not abusing their limited statutory authority to meet political objectives. Accordingly, we urge the Departments to withdraw the proposed 4-Month STLDI Definition because they lack authority to regulate

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[29] Proposed Rule at 44,648 (cols. b-c).

[30] *Id.* at 44,610 (col. a) ("As of January 20, 2020, 12 States had enacted legislation prohibiting health status underwriting for STLDI, effectively banning the sale of STLDI in those States[.] Thirteen States and the District of Columbia prohibited the sale of STLDI policies with initial contract terms longer than 3 months.").

[31] It bears mention too that ACA premium rates have remained stable especially in markets where STLDI has been available for longer terms, whereas in other markets forecasting increased ACA exchange premium rates in the future attribute those increases in inflation, rising prescription drug costs, and more, not the STLDI consumer option. If premiums continue to rise in these markets—and especially as consumers confront the expiration of ACA subsidies in 2025—consumers may be left without the STLDI option Congress intended due to unreasonable, and therefore avoidable, agency action.

[32] *See Central United Life v. Burwell*, 827 F.3d 70, 73 (2016) ("*Central United*") ("HHS's attempt to regulate consumers under a provision directed at providers confirms the agency's rule was an act of amendment, not interpretation. Accordingly, HHS has no colorable claim to *Chevron* deference.") (Citing *MCI Telecomm. Corp. v. AT&T Co.*, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

consumer behavior in this way, and because the Departments lack authority to disturb a state's ability to regulate its own insurance industry.

For the reasons explained above, we urge the Departments to refrain from re-writing Congress's statute by inventing an extra-statutory 4-Month Definition of STLDI that will unlawfully affect consumers' access to STLDI as Congress intended.

6. Inventing time-limitations purportedly derived from one statute in order to serve the political interests contemplated under a separate statute enacted decades later is unreasonable and an abuse of discretion.

Apart from the Departments' unlawful attempt to draft federal legislation reserved for Congress alone, the obvious strategy to coerce individuals into purchasing comprehensive health insurance coverage regulated directly or indirectly by the ACA is improper. The language of section 2791(b)(5) of the PHS Act, and even the regulatory interpretation set forth in 1997 giving original meaning to STLDI (*i.e.*, "less than 12 months after the original effective date of the contract") predates the ACA, its influence over the commercial insurance market, and current trends in risk, premium rate setting, and risk adjustment by nearly two decades. "[W]e will not understand Congress to have amended [a prior] act by implication unless there is a positive repugnancy between the provisions of the preexisting and newly enacted statutes, as well as language manifesting Congress's considered determination of the ostensible change." *U.S. Ass'n of Reptile Keepers, Inc. v. Zinke*, 852 F.3d 1131, 1141 (D.C. Cir. 2017) (internal quotation marks omitted). Further, even though Congress had the option to amend or modify this provision in the course of enacting the ACA, it did not.

Stated simply, no amount of regulatory "reflection," nor tortured regulatory re-writing of this decades-old statutory provision in clear attempt to circumvent Congressional action, will pass legal muster, and will fail as a matter of law.[33]

B. "PER-PERIOD" EXCLUSIVITY FOR FIXED INDEMNITY PLANS.

The Proposed Rule likewise creates an entirely new and extra-statutory limitation for hospital indemnity and other fixed indemnity insurance to qualify as an excepted benefit in the group health insurance market by amending existing regulations at 26 C.F.R. § 54.9831-1(c)(4), 29 C.F.R. § 2590.732(c)(4), and 45 C.F.R. § 146.145(b)(4), and to the individual market at 45 C.F.R. § 148.220(b)(4).[34] By exempting less than what the statute explicitly permits, Departments will again trespass unlawfully into a role reserved for Congress and Congress alone. In so doing, the Departments propose that fixed indemnity excepted benefits coverage in the individual market

[33] Notably, six bills containing modifications to STLDI failed between 2019 and 2021. *See, e.g.*, H.R. 987, 116th Congress (2019); S. 1566, 116th Congress (2019); H.R. 1010, 116th Congress (2019), H.R. 1425, 116th Congress (2019); S. 352, 116th Congress (2021); S. 942, 116th Congress (2021). In addition, one bill designed to eliminate STLDI altogether failed in the 2021-2022 session. *See* H.R. 1875, 117th Congress (2021).

[34] *Id.* at 44,619 (col. c).

must only provide benefits that are paid only on a "per-period" basis, and prohibit "per-service" and "per-item" reimbursement arrangements that have served consumer needs for decades.[35]

Under Section 2791(c) of the PHS Act, certain health plans that provide coverage on a fixed indemnity basis may be "excepted" from the ACA's market reform requirements if specific conditions are met. Congress defined these conditions in clear and unambiguous terms – in order to qualify as an excepted benefit, a fixed indemnity plan must be 1) provided under a separate policy, certificate, or contract of insurance, and 2) offered as independent and noncoordinated benefits.[36] The Departments ignore this Congressional-mandated and controlling definition in the authorizing statute and propose to re-write the statute with new regulations. Codifying regulations in this way amount to nothing more than a creative approach to evade the Departments' (and specifically, HHS's) past failures in the courtroom that implicated nearly identical, extra-statutory agency maneuvers.

If finalized in its current form, the Proposed Rule would require fixed indemnity plans in both the group and individual markets to pay benefits "in a fixed dollar amount per day (or other time period of hospitalization) regardless of the actual or estimated amount of expenses incurred, services or items received, severity of illness or injury experienced by a covered participant or beneficiary, or other characteristics particular to a covered participant or beneficiary, and not on any other basis (such as on a per-item or per-service basis)."[37] The Proposed Rule would further restrict fixed indemnity plans in the group market, by imposing an overly-broad definition of "coordination" that would effectively prohibit even informal "coordination"—a practice that Congress clearly never intended to prohibit. Finally, the Proposed Rule would narrow these statutory criteria for fixed indemnity plans in order to strip these plans of the features that make them beneficial and appropriate for many consumers. The outcome of this extra-statutory rulemaking will almost certainly result in the eradication of a much-needed health insurance product, thereby categorically depriving consumers of per-item or per-service fixed indemnity options that best fit their coverage needs.

However, the Departments lack the authority to implement the restricting criteria for the following reasons: (1) the authorizing statute set forth in section 2791(c) of the PHS Act does not grant the Departments authority to add new criteria for fixed indemnity plans on the individual market (2) the authorizing statute does not delegate authority to prohibit consumers from enrolling in fixed indemnity plans alongside other plans in the group market, (3) the Departments have already tried and failed to put forth similar restrictions on fixed indemnity plans; (4) the consumer protection reasons the Departments cite to justify their definitional changes to the fixed indemnity statute are unsupported by substantial evidence; and (5) the Departments concerns regarding misconduct in the fixed indemnity insurance market are matters of state law, not federal law.

1. <u>The authorizing statute set forth in Section 2791(c) of the PHS Act does not grant the Departments authority to add new criteria for fixed indemnity plans in the individual market.</u>

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[35] *Id.* at 44,620 (col. b).

[36] *See* 42 U.S.C. § 2791(c). *See also* 42 U.S.C. §§ 300gg-63(b), 300gg-91(c)(3), 300gg-21(c)(2).

[37] Proposed Rule at 44, 651 (col. b), 657 (col. c) (July 12, 2023).

The Departments lack authority to unilaterally define how benefits may be provided for fixed indemnity plans on the individual market under section 2791(c) of the PHS Act. This statutory provision *only* provides that hospital indemnity or other fixed indemnity insurance will be considered excepted benefits if issued as a separate policy and "offered as independent, noncoordinated benefits."[38] Unlike in the group market, subsequent regulations did not expand the statutory definition in a manner that would prohibit choice in how benefits are provided.

Under the Proposed Rule, the Departments flout the controlling Congressional statute by proposing to amend the statutory definition of fixed indemnity plan with extra-statutory criteria created out of whole cloth. These criteria will now dictate *how* plans may provide benefits by foreclosing them from consideration as an excepted benefit, without even a scintilla of Congressional authority existing in the underlying statute. More specifically, the Departments nakedly propose that benefits must only be paid "in a fixed dollar amount per day (or other time period of hospitalization) regardless of the actual or estimated amount of expenses incurred, services or items received, severity of illness or injury experienced by a covered participant or beneficiary, or other characteristics particular to a covered participant or beneficiary, and not on any other basis (such as on a per-item or per-service basis)."[39]

Congress established clear and unambiguous criteria for what constitutes a fixed indemnity plan: the plan must be 1) provided under a separate policy, certificate, or contract of insurance, and 2) offered as independent and noncoordinated benefits.[40] Nowhere does the statute indicate *how* benefits may be delivered, including whether delivered on a "per-period" or "per-service" basis. In addition, and specifically concerning fixed indemnity plans at issue in the Proposed Rule, the D.C. Circuit Court of Appeals has ruled that the Departments may not "tack on additional criteria" to the definition of fixed indemnity, which would have the effect of limiting the range of fixed indemnity insurance from consideration as an excepted benefit. That decision in *Central United* is controlling here: "Where Congress exempted all such conforming plans from the PHSA's coverage requirements, HHS, with its additional criterion, exempts less than all. Disagreeing with Congress's expressly codified policy choices isn't a luxury administrative agencies enjoy."[41] The Proposed Rule's extra-statutory mandate that benefits must now only be provided on a "per-period" basis, but no longer on a "per-item" or "per-service" basis – both of which have been lawful for decades under both state and federal law – stands in direct conflict with the enabling statute (HIPAA), the rules of statutory construction, and controlling legal precedent. In short, the Proposed Rule "exempts less than all," which flies in the face of the D.C. Circuit's controlling decision in *Central United.* We are therefore mystified at the Departments latest attempts at "coloring outside the lines of [their] authority,"[42] let alone enjoying a "luxury" not available for them to "enjoy." The Departments should decline this approach.

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[38] *See* 42 U.S.C. § 2791(c).

[39] 88 Fed. Reg. 44, 651 (col. b), 657 (col. c) (July 12, 2023).

[40] *See* 42 U.S.C. § 2791(c).

[41] *Central United*, 827 F.3d 70, 73.

[42] *Id.* ("Nothing in the PHSA suggests Congress left any leeway for Congress to tack on additional criteria [to the definition of fixed indemnity].)

2. The authorizing statute does not delegate authority to prohibit consumers from enrolling in fixed indemnity plans alongside other plans in the group market.

The Proposed Rule would also prohibit group fixed indemnity excepted benefit coverage from coordinating with an exclusion of benefits under a group health plan sponsored by the same plan sponsor. (The Departments propose a similar prohibition for the individual market.) However, the Departments lack authority to redefine these criteria under section 2791(c) of the PHS Act. The only prohibition Congress expressly enacted concerns the "coordination between the provision of [fixed indemnity excepted] benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor."[43] This requirement prohibits formal arrangements in which plan sponsors design and offer plans that are intended as complementary, and consumers enroll in these plans under a formal arrangement, such that the benefits provided under one plan complement the benefits that are excluded under the other plan.

Notwithstanding the Departments' exceedingly limited statutory authority, they nevertheless attempt to further define this standard by prohibiting arrangements that may be deemed to be an "informal" coordination of benefits, even though the authorizing statute only prohibits a *formal* arrangement. The Proposed Rule would also prohibit instances in which a plan sponsor offers multiple benefit packages (one of which is a fixed indemnity plan), and an employee enrolls in the fixed indemnity plan, along with another plan that provides minimum essential coverage benefits, but is not comprehensive. A restriction of this type not only violates the plain language of the statute, but also creates an entirely unreasonable reading of the text. There are few, if any, fixed indemnity plans on the group market that would meet the proposed criteria, and as such, the Proposed Rule would effectively discard whole sections of the underlying statute that authorize fixed indemnity plans on the group market in the first place. Congress meant what it wrote.

As with other provisions in the Proposed Rule, the Departments again lack authority to implement this prohibition. If a plan sponsor chooses to offer an array of plan options, and a consumer elects to pick-and-choose from among those options to address their specific needs, no reasonable person would agree that this arrangement resembles the type of formal "coordination" contemplated in the authorizing statute, because any perceived coordination is simply incidental to the choices that the consumer elects. The Departments' attempt to redefine the term "coordination" to prohibit these informal arrangements is clearly unreasonable, and in any event, entirely circumvents Congressional intent.

3. The Departments have already tried and failed to put forth similar restrictions on fixed indemnity plans.

In 2016, the Departments proposed similar regulations that attempted to further define the standards for fixed indemnity plans in both the group and individual markets.[44] These regulatorily-proposed criteria included the proposed codification of two illustrative examples that would have mandated that benefits be provided on a "per-period" basis for plans in the group market. At that time, the Departments also solicited comments as to whether the criteria for fixed indemnity

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[44] *See* 81 Fed. Reg. 38,019 (June 10, 2016).

benefits to be considered excepted benefits should be more closely aligned between the group and individual markets.[45] But after considerable pushback from commenters and industry, which included opposition from both individual state regulators and the collective National Association of Insurance Commissioners (among others), CMS did not finalize the proposed changes.

The Proposed Rule here goes even further than the 2016 proposal in that it would make unprecedented and unlawful changes to the criteria for individual market plans and codify three examples to clarify how benefits should be provided on a per-period basis for group plans. Again, in view of the clear and unambiguous statutory provisions enacted by Congress, and as reinforced by the D.C. Court of Appeals in *Central United*, we are mystified at the Departments latest attempts to re-write a Congressional statute and "color[] outside the lines of [their] authority,"[46] let alone enjoying a "luxury" not available for them to "enjoy." As before in 2016, the Departments should decline this new attempt at drafting legislation, which is an exercise reserved for Congress.

4. The consumer protection reasons the Departments cite to justify their definitional changes to the fixed indemnity statute are unsupported by substantial evidence.

The Departments assert that the new proposed criteria for fixed indemnity excepted benefit plans will help protect consumers from misleading marketing practices and encourage consumers to enroll in comprehensive plans through the ACA marketplace.[47] According to the Departments, consumers may elect a fixed indemnity plan, believing that the plan provides comprehensive coverage, only to later find that the plan inadequately covers their medical expenses.[48]

This reasoning is misguided for several reasons. First, the Departments have failed to put forth meaningful evidence the alleged abuses are in fact occurring with fixed indemnity products. The Departments allege (without substantial corroborating evidence), that companies (or agents/brokers) marketing and selling fixed indemnity products mislead consumers into believing they are purchasing comprehensive health plans, and then leave these consumers in financial ruin once the consumers need to exercise the benefits under their plan.

Resorting to hysteria hardly characterizes the reality of how actual consumers evaluate and purchase fixed indemnity plans. Moreover, apart from a few studies that address *potential* concerns with fixed indemnity plans, the Departments offer no serious, quantitative evidence indicating that consumers actually experience harm as a result of enrolling in these plans.[49] In fact, a recent report surveying carriers in the fixed indemnity market found that while over nine (9) million individuals are currently enrolled in fixed indemnity plans, the rate of complaints per

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[45] *Id.*

[46] *Central United*, 827 F.3d 70, 73 ("Nothing in the PHSA suggests Congress left any leeway for Congress to tack on additional criteria [to the definition of fixed indemnity].).

[47] Proposed Rule at 44,596, 44,605-06.

[48] *Id.*

[49] *Id.* at 44,619 (col. b)

fixed indemnity policy/certificate is 0.0003.[50] Actual market reporting data—not armchair analyses or regulatory "reflections"—reveal that consumers enrolled in fixed indemnity plans clearly find value in these plans and do not experience the type of egregious practices that the Departments argue characterize the whole of the fixed indemnity market.

Further, the changes that the Departments propose will limit consumer choice and almost certainly leave consumers who cannot afford comprehensive plans—or know that such plans do not meet their or their families' unique coverage needs—without any coverage at all. The Departments' proposed timing for implementing these new plan requirements is particularly troubling, with millions of currently enrolled consumers potentially losing their coverage on January 1, 2027.

5. The Departments concerns regarding misconduct in the fixed indemnity insurance market are matters of state law, not federal law.

Again in the service of meeting political objectives, the Proposed Rule's fixed indemnity amendments flout individual state rights to regulate insurance independently, and without any meaningful analysis of existing and/or conflicting constitutional and/or state laws or regulations.[51] And again, the agency's misleading characterization of its "Federalism" analysis amounts to mere lip service because it relies on the false premise that the new criteria proposed for the fixed indemnity market are proper.[52] They are not. The Departments' effort to rewrite the statute in order to re-define fixed indemnity plans will have a profound and significant effect on the *business* of health insurance taking place in individual state insurance markets, which is ultimately consumer-driven, and therefore concern matters under state law.

Nothing in the Proposed Rule indicates or suggests that individual states have been ineffective in their regulations of either STLDI or fixed indemnity markets (or of producers who sell these plans), why individual states should be deprived of the opportunity to regulate fixed indemnity plans within the scope of their own authority (as they have effectively regulated for decades, even prior to the enactment of HIPAA in 1996), or why the Departments have license to intrude upon on state regulations concerning fixed indemnity that is not subject to the Federal consumer protections and requirements for comprehensive coverage that apply to individual health insurance coverage. The fact remains that the underlying statute here was not intended to regulate consumers, but rather, insurance plans. Applying new "per-period" payment criteria, imposing an overly-broad definition of "coordination," and narrowing statutory criteria for fixed indemnity plans in order to strip these plans of the features that make them beneficial and appropriate for many consumers are acts of amendment, not permissible statutory interpretation.[53]

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[50] *See* AHIP-ACLI-BCBSA 2023 Survey: Fixed Indemnity & Specified Disease Plans, conducted on July 30, 2023 to Sept. 7, 2023; published Sept. 8, 2023.

[51] *See, e.g.*, U.S. Const., Art. I § 8, cl. 3 (the "Commerce Clause"); The McCarran-Ferguson Act of 1945, 15 U.S.C. § 1101-1105 *et seq.*, *United States v. South-Eastern Underwriters Ass'n*, 322 U.S. 533 (1944); The Sherman Antitrust Act of 1890, 15 U.S.C. §§ 1-7.

[52] Proposed Rule at 44,648 (cols. b-c).

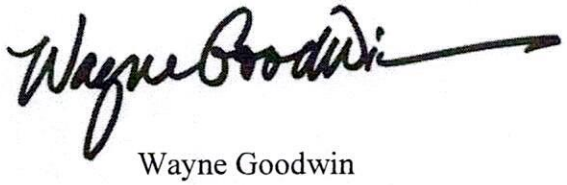
[53] *See Central United*, 827 F.3d 70, 74 ("HHS's attempt to regulate consumers under a provision directed at providers confirms the agency's rule was an act of amendment, not interpretation. Accordingly, HHS has no colorable claim to *Chevron* deference.") (Citing *MCI Telecomm. Corp. v.*

Moreover, while we share the Departments' concerns about fraudulent, deceptive, or otherwise misleading marketing efforts, these concerns are not solved by through unlawful agency rulemaking. Instead, the Departments should focus their attention on ways to enforce existing legal authorities, both state and federal, to combat illegal marketing schemes, not abusing their discretion to meet political objectives and threaten consumer choice. Accordingly, we urge the Departments to withdraw the amendments to the definition of fixed indemnity in the Proposed Rule because the Departments lack authority to limit consumers' access to fixed indemnity plans as Congress intended, and because the Departments lack authority to disturb a state's ability to regulate its own insurance industry.

* * *

For the reasons stated above, we urge the Departments to abandon this Proposed Rule as drafted and reject the temptation to overstep the clear limits of authority reserved for Congress and Congress alone.

Sincerely,



Wayne Goodwin

Executive Director (Interim)

AT&T Co., 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN ASSOCIATION OF ANCILLARY BENEFITS, A FLORIDA NOT-FOR-PROFIT CORPORATION,	§	
Plaintiff,	§	**Case No. 24-CV-783**
	§	**Honorable Judge Sean D. Jordan**
v.	§	
XAVIER BECERRA, in his official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, JULIE A. SU, in her official capacity, as acting UNITED STATES SECRETARY OF LABOR, and JANET YELLEN, in her official capacity, as SECRETARY OF THE UNITED STATES DEPARTMENT OF THE TREASURY,	§	
Defendants.	§	

ORDER FOR PLAINTIFF'S MOTION FOR LEAVE TO FILE BRIEF IN EXCESS OF PAGE LIMITATION REQUIREMENTS

The court has considered Plaintiff's Motion for Leave to File Brief in Excess of Page Limitation Requirements. For the reasons stated on the record:

It is ORDERED that:

□ The Plaintiff's Motion for Leave to File Brief in Excess of Page Limitation Requirements is GRANTED.

□ The Plaintiff's Motion for Leave to File Brief in Excess of Page Limitation Requirements is DENIED.

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DATE PRESIDING JUDGE