

**OFFICE OF PERSONNEL
MANAGEMENT****5 CFR Part 890**

RIN 3206–AO28

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[REG–114676–21]

RIN 1545–BQ15

DEPARTMENT OF LABOR**Employee Benefits Security
Administration****29 CFR Part 2590**

RIN 1210–AC08

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****45 CFR Parts 144, 148, 149, and 150**

[CMS–9907–P]

RIN 0938–AU61

**Requirements Related to Air
Ambulance Services, Agent and
Broker Disclosures, and Provider
Enforcement**

AGENCY: Office of Personnel Management; 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: Proposed rules.

SUMMARY: This document sets forth proposed rules implementing certain provisions of Title I (No Surprises Act) and Title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (CAA). These proposed rules would amend and add provisions to existing rules under the Internal Revenue Code (Code), the Employee Retirement Income Security Act (ERISA), the Public Health Service Act (PHS Act), and the Federal Employees Health Benefits (FEHB) Act. These proposed rules would implement certain provisions of the No Surprises Act that would increase transparency by requiring group health plans and health insurance issuers in the group and individual markets, and FEHB carriers, to submit certain information about air ambulance services to the Secretaries of Health and Human Services (HHS),

Labor, and the Treasury, and the Director of the Office of Personnel Management, as applicable, and by requiring providers of air ambulance services to submit certain information to the Secretaries of HHS and Transportation. These proposed rules also include HHS-only proposed rules that would increase transparency by requiring a health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance to disclose to policyholders and to report to HHS any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage. These proposed rules would also provide the process by which HHS would investigate complaints and potential violations of PHS Act provisions and, if warranted, take enforcement action, including the imposition of civil money penalties, against providers and facilities, including providers of air ambulance services. These proposed rules would amend existing regulations to clarify the process to investigate complaints and potential violations of the PHS Act and impose civil money penalties against plans and issuers. These proposed rules would also establish the process by which HHS would impose civil money penalties if a provider of air ambulance services fails to submit some or all required data to HHS.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by October 18, 2021.

ADDRESSES: In commenting, please refer to file code CMS–9907–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9907–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9907–P, Mail

Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For matters related to air ambulance reporting: Padma Babubhai Shah, Office of Personnel Management, (202) 606–4056; Kari DiCecco, Internal Revenue Service, Department of the Treasury, (202) 317–5500; Matthew Meidell or Pinar Shapiro, Employee Benefits Security Administration, Department of Labor, (202) 693–8335; Christina Whitefield, Centers for Medicare & Medicaid Services, Department of Health and Human Services, (301) 492–4172. For matters related to agent and broker disclosures under Part 148: Adam Wheeler, (410) 786–3942.

For matters related to enforcement under Part 150: Judah Katz, (410) 786–3879 or Lisa Cuzzo, (410) 786–1746.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. The Centers for Medicare & Medicaid Services (CMS) will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background**A. Legislative and Regulatory Overview**

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added Title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets. 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 known as the “Affordable Care Act” or “ACA.”) 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 term “group health plan” includes both insured and self-insured group health plans. The ACA added section 9815(a)(1) to the Internal Revenue Code (Code) and section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) to incorporate the provisions of Part A of Title XXVII of the PHS Act into the Code and ERISA, and made them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. Sections 2701 through 2728 of the PHS Act are thereby incorporated into the Code and ERISA.

The Consolidated Appropriations Act, 2021 (CAA) was enacted on December 27, 2020 and includes Title I (No Surprises Act) and Title II (Transparency) in Division BB. The CAA added provisions that apply to plans and issuers offering group or individual health insurance coverage in chapter 100 of the Code, in part 7 of ERISA, and in a new Part D of Title XXVII of the PHS Act. The CAA also amended the Federal Employees Health Benefits (FEHB) Act, 5 U.S.C. 8901, *et seq.*, by adding a new subsection (p) to 5 U.S.C. 8902 that requires each contract with an FEHB carrier to require the carrier to comply with requirements described in certain provisions of the Code, ERISA, and the PHS Act in the same manner as those provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage. The CAA provisions that apply to providers, facilities, and providers of air ambulance services, such as requirements related to cost sharing, prohibitions on balance billing for certain items and services, and requirements related to disclosures about balance billing protections, were added to Title XXVII of the PHS Act in a new Part E.

Section 106(a) of the No Surprises Act requires providers of air ambulance services to report certain information to the Secretaries of HHS and Transportation. Section 106(b) of the No Surprises Act added parallel provisions at section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act. These provisions include requirements for plans and issuers to report claims and other information regarding air ambulance services and providers of air ambulance services.

The Director of the Office of Personnel Management (OPM) is of the

view that the collection of FEHB plan air ambulance claims data is necessary and appropriate for a more complete understanding of air ambulance services provided across the industry. Further, the OPM Director is of the view that this data would inform OPM for purposes of enforcing the protections provided under 5 U.S.C. 8902(p) and for the appropriate administration and oversight of FEHB plans.

Sections 106(a) and (b) of the No Surprises Act impose these air ambulance data reporting requirements for 2 years. Section 106(c) of the No Surprises Act further requires HHS, in consultation with the Secretary of Transportation, to issue a comprehensive public report summarizing the data and providing an assessment of the state and certain aspects and characteristics of the air ambulance market. Section 106(e) of the No Surprises Act provides for the imposition of civil money penalties of not more than \$10,000 on providers of air ambulance services for failure to submit required data. Section 106(e)(3) specifies that certain provisions of section 1128A of the Social Security Act (SSA) shall apply to a civil money penalty under section 106(e) of the No Surprises Act in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the SSA. In addition, section 418 of the Federal Aviation Administration (FAA) Reauthorization Act of 2018¹ directs the Secretary of Transportation, in consultation with HHS, to form an Advisory Committee on Air Ambulance and Patient Billing (Advisory Committee). Section 106(d) of the No Surprises Act directs HHS, in consultation with the Secretary of Transportation, to take into consideration (as applicable and to the extent feasible) any recommendations included in the Advisory Committee’s report.

The charter of the Advisory Committee allowed for the formation of subcommittees to perform specific assignments. The Advisory Committee formed three subcommittees, which included a subcommittee on the Prevention of Balance Billing. At its second full Committee meeting in May 2021, the Advisory Committee recommended the collection of eight specific data elements from providers of air ambulance services: (1) Average cost per trip; (2) air ambulance base rates and patient-loaded statute mileage rates; (3) ancillary fees for specialty services, like neonatal, cardiac, and “other” (for example, specialized medicines like

¹ Public Law 115–254.

snakebites in rural areas); (4) reimbursement data aggregated by payor type (Medicare, Medicaid, self-insured, private insurance) and per transport, based on median rate and zip code, as well as further identifying data regarding private insurance by provider type (hospital-sponsored program, municipality-sponsored program, hospital independent partnership (hybrid) program, or independent program); (5) alternate revenue sources (for example, subsidies or membership programs) broken down per transport for reporting purposes; (6) volume of transports, segregated by aircraft type (fixed wing and rotary wing) and takeoff zip code for government purposes, or for public use when aggregated with other data; (7) market share for air transport, obtained from the FAA certificate holder and identifying the certificate holder’s parent company; and (8) market share for health care, by looking at the program type for the FAA certificate holder.² Section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act require information to be reported jointly to HHS, the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments).

Section 106(d) of the No Surprises Act requires HHS, in consultation with the Secretary of Transportation, to undertake notice and comment rulemaking to specify the form and manner in which plans and issuers must submit this information.

The CAA amended the FEHB Act to require that protections from air ambulance surprise billing must be offered by carriers in the same manner as those protections apply under section 9817 of the Code, section 717 of ERISA, and section 2799B–2 of the PHS Act and to require that protections from surprise billing by providers of air ambulance services with respect to FEHB enrollees apply in the same manner as those protections apply under section 2799B–5 of the PHS Act.

The CAA also amended Title XXVII of the PHS Act to add section 2746, which requires a health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance to disclose to enrollees in such coverage and to report annually to HHS the direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling

² “Meeting Summary, Second Meeting of the AAPB Advisory Committee,” U.S. Department of Transportation, Air Ambulance and Patient Billing Advisory Committee, May 27–28, 2021, Washington, DC pp. 15–17. Available at: <https://www.transportation.gov/sites/dot.gov/files/2021-07/AAPB%20Second%20Meeting%20Minutes.pdf>.

individuals in such coverage. Section 2746(d) directs HHS to finalize, through notice and comment rulemaking, the timing, form, and manner in which issuers must make these disclosures to consumers and submit reports to HHS. These new statutory requirements are applicable beginning December 27, 2021.

Section 2723(b) of the PHS Act, as amended by the CAA, authorizes HHS to impose civil money penalties as a means of enforcing the individual and group market requirements contained in Part A and Part D of Title XXVII of the PHS Act with respect to health insurance issuers when a state fails to substantially enforce these provisions, as well as with respect to group health plans that are non-Federal governmental plans.³ Section 2799B-4 of the PHS Act, as added by section 104 of the No Surprises Act, establishes a similar framework for HHS's enforcement authority over providers and facilities, including providers of air ambulance services, in states that fail to substantially enforce the requirements of Part E of Title XXVII of the PHS Act, as added by the CAA. This provision also authorizes HHS to impose civil money penalties of up to \$10,000 per violation on providers and facilities, including providers of air ambulance services, that fail to comply with the applicable PHS Act requirements in such states. It further provides that certain provisions of section 1128A of the SSA shall apply to a civil money penalty or assessment under section 2799B-4 of the PHS Act in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a) of section 1128A of the SSA.

The Departments are issuing regulations in several phases implementing provisions of Title I (No Surprises Act) and Title II (Transparency) of Division BB of the CAA. Later this year, the Departments intend to issue regulations regarding the Federal independent dispute resolution (IDR) process (sections 103 and 105 of the No Surprises Act) and patient protections through transparency and the patient-provider dispute resolution process (section 112 of the No Surprises Act).

On July 13, 2021, the Departments and OPM issued interim final rules entitled *Requirements Related to*

Surprise Billing; Part I,⁴ which generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022; FEHB health benefits plans with respect to contract years beginning on or after January 1, 2022; and health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022 (July 2021 interim final rules). The July 2021 interim final rules implement sections 9816(a)-(b) and 9817(a) of the Code; sections 716(a)-(b) and 717(a) of ERISA; sections 2799A-1(a)-(b), 2799A-2(a), 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the PHS Act; and 5 U.S.C. 8902(p), to protect consumers from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers of air ambulance services, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances.

Among other requirements, the July 2021 interim final rules require emergency services to be covered without any prior authorization, without regard to whether the health care provider or facility furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services, and without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits or a permitted affiliation or waiting period. With respect to emergency services furnished by nonparticipating providers or facilities, air ambulance services furnished by nonparticipating providers of air ambulance services, and non-emergency services furnished by nonparticipating providers at certain participating facilities, the July 2021 interim final rules generally limit cost sharing for out-of-network services to in-network levels, require such cost sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibit balance billing in certain circumstances. Balance billing refers to the practice of out-of-network providers billing patients for the difference between: (1) The provider's billed charges; and (2) the amount collected from the plan or issuer plus the amount collected from the patient in the form of cost sharing (such as a

copayment, coinsurance, or amounts paid toward a deductible).

Division BB of the CAA also includes: Provisions regarding transparency in plan and insurance identification cards (section 107); continuity of care (section 113); accuracy of provider network directories (section 116); prohibition on gag clauses (section 201) that are applicable for plan years beginning on or after January 1, 2022; and pharmacy benefit and drug cost reporting (section 204) that is required by December 27, 2021. The Departments intend to undertake rulemaking to fully implement these provisions, but rules regarding some of these provisions might not be issued until after January 1, 2022. The Departments note that any such rulemaking to fully implement these provisions would include a prospective applicability date that provides plans, issuers, providers, and facilities, as applicable, a reasonable amount of time to comply with new or clarified requirements. Until rulemaking to fully implement these provisions is finalized and effective, plans and issuers are expected to implement the requirements using a good faith, reasonable interpretation of the statute.

B. Stakeholder Consultation and Input

The Departments consulted with stakeholders on policies related to Division BB of the CAA, including air ambulance data collection, disclosure and reporting of agent and broker compensation, and enforcement of the PHS Act. The Departments held several listening sessions with consumers, health care providers, facilities, providers of air ambulance services, employers, agents, brokers, health plans and health insurance issuers, advocacy groups, and the actuarial community to gather public input. The Departments also solicited input from state representatives on numerous relevant topics and consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), and regular contact with state regulators, issuers, trade groups, consumer advocates, employers, and other interested parties. The Departments considered all public input received as the Departments developed the policies in these proposed rules and welcome additional public comment as part of these proposed rules.

C. Structure of Proposed Rules

The regulations outlined in these proposed rules would be codified in 5 CFR part 890; 26 CFR part 54; 29 CFR part 2590; and 45 CFR parts 144, 148, 149, and 150.

³ Also see section 2761 of the PHS Act, which establishes a parallel framework for enforcement of the individual market requirements contained in Part B of Title XXVII of the PHS Act.

⁴ Requirements Related to Surprise Billing; Part I, 86 FR 36872, (July 13, 2021). Public comments on this rule are due by September 7, 2021.

The proposed changes to 45 CFR part 144 would make technical and conforming amendments regarding the purpose of part 150.

The proposed changes to 45 CFR part 148 would set forth requirements for health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to disclose to policyholders information regarding direct and indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage. The proposed amendments to 45 CFR part 148 also set forth proposed requirements related to the annual reports that health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance would be required to submit to HHS regarding the direct and indirect compensation paid to agents and brokers. In addition, these proposed rules would make technical and conforming amendments regarding the basis, purpose, and scope of 45 CFR part 148.

The proposed changes to 45 CFR part 149 would require plans, issuers, and providers of air ambulance services to submit to HHS certain data regarding air ambulance services. Proposed rules under 26 CFR 54.9823–1 and 29 CFR 2590.723 would provide that group health plans and health insurance issuers offering group health insurance coverage that satisfy the requirements under 45 CFR part 149 that implement section 2799A–8 of the PHS Act would be treated as satisfying the parallel requirements under section 9823 of the Code and section 723 of ERISA. The proposed change to 5 CFR part 890 would require FEHB carriers to comply with the requirements of 45 CFR 149.230 with respect to an FEHB plan in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage. OPM would coordinate with HHS to receive FEHB air ambulance services data.

The proposed changes to 45 CFR part 150 would make procedural changes to the process HHS utilizes to investigate possible violations of the PHS Act, including proposed amendments to clarify the process to investigate complaints and potential violations of the PHS Act and to impose civil money penalties against non-Federal governmental plans and issuers of group or individual health insurance coverage. The proposed changes would also set forth the process for imposing civil money penalties on providers and facilities, including providers of air

ambulance services, for failure to comply with 45 CFR part 149 and failure to provide data required in section 106(a) of the No Surprises Act.

II. Provisions of the Proposed Rules on Reporting Requirements Regarding Air Ambulance Services—Departments of HHS, Labor, and the Treasury

A. In General

These proposed rules propose requirements related to data collection from providers of air ambulance services, as required by section 106(a) of the No Surprises Act, and from plans and issuers offering group or individual health insurance coverage, as required by section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act, as added by section 106(b) of the No Surprises Act.

These proposed rules also include an HHS-only proposed rule that sets forth civil money penalties specified in section 106(e) of the No Surprises Act that would apply to providers of air ambulance services for failure to submit data as required under section 106(a) of the No Surprises Act.⁵

Air ambulance services frequently result in surprise medical bills due to individuals' inability to select an in-network provider of air ambulance services when faced with an urgent medical situation. Because of low network participation rates by providers of air ambulance services, individuals are also unable to avoid potential higher cost sharing and balance billing by out-of-network providers. A 2019 study by the Government Accountability Office (GAO) analyzed data from 2017 and found that 69 percent of air ambulance transports of privately-insured patients were out-of-network.⁶

When individuals are unable to avoid providers or providers of air ambulance services that are not in their plan's network, it raises health care costs and exposes individuals to financial risk.⁷ The ability to balance bill is often used as leverage by providers to obtain higher in-network payments, which results in

⁵ Section 106(b) of the No Surprises Act amends part D of Title XXVII of the PHS Act by adding new section 2799A–8. As such, the enforcement provisions under PHS Act section 2723 and 45 CFR part 150 extend to PHS Act section 2799A–8 air ambulance data reporting requirements on issuers and non-Federal governmental group health plans. Section 106(a) of the No Surprises Act is codified in the United States Code as a note to PHS Act section 2799A–8.

⁶ *Air Ambulance: Available Data Show Privately-Insured Patients Are at Financial Risk*. GAO–19–292 (March 2019).

⁷ Cooper Z et al., *Out-of-Network Billing and Negotiated Payments for Hospital-Based Physicians*, Health Affairs 39, No. 1, 2020. doi: 10.1377/hlthaff.2019.00507.

higher premiums, higher cost sharing for consumers, and overall increased health care expenditures.⁸ Studies have shown that surprise medical bills can be substantial, including with respect to air ambulance services. The GAO found that for privately-insured patients, the median price charged by providers of air ambulance services was about \$36,400 for a rotary-wing transport and \$40,600 for a fixed-wing transport in 2017.⁹ In an earlier study,¹⁰ the GAO noted that there is no national data on balance billing and the extent to which providers of air ambulance services have contracts with health insurance companies. Some states have attempted to collect data on balance billing. The GAO study stated that a Michigan state review of 19 cases of balance billing for air ambulance services between 2013 and 2016 showed an average balance bill of \$31,000. Data on cases investigated and closed by the Maryland Insurance Administration between January 2014 and April 2018 showed that the amount of balance bills for air ambulance services ranged from \$12,300 to \$52,000.

Although some states have enacted laws to regulate the billing practices of providers of air ambulance services, many of these efforts have been unsuccessful due to a preemption provision in the Airline Deregulation Act of 1978 (ADA). The ADA states, in relevant part, “. . . a State, political subdivision of a State, or political authority of at least two States may not enact or enforce a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier that may provide air transportation under this subpart.”¹¹ Assuming that a provider of air ambulance services is an “air carrier” covered by this provision, as is typical,¹² the provision preempts state

⁸ See, Cooper, Z. et al, *Surprise! Out-Of-Network Billing For Emergency Care in the United States*, NBER Working Paper 23623, 20173623; Duffy, E. et al., “Policies to Address Surprise Billing Can Affect Health Insurance Premiums.” *The American Journal of Managed Care* 26.9 (2020): 401–404; and Brown E.C.F., et al., *The Unfinished Business of Air Ambulance Bills*, Health Affairs Blog (March 26, 2021), DOI: 10.1377/hblog20210323.911379, available at <https://www.healthaffairs.org/doi/10.1377/hblog20210323.911379/full/>.

⁹ *Air Ambulance: Available Data Show Privately-Insured Patients Are at Financial Risk*. GAO–19–292 (March, 2019).

¹⁰ *Air Ambulance: Data Collection and Transparency Needed to Enhance DOT Oversight*. GAO–17–637 (July 27, 2017).

¹¹ 49 U.S.C. 41713(b).

¹² A provider of air ambulance services is a covered “air carrier” if it has economic authority from the Department of Transportation to provide interstate air transportation. Most providers of air ambulance services have such authority under the

laws that would limit the amount of payment that the provider of air ambulance services would otherwise be entitled to receive.¹³ Even within states that have enacted protections against surprise billing, state insurance regulations typically apply only to health insurance coverage, as ERISA generally preempts state laws that would otherwise regulate self-insured group health plans sponsored by private employers.¹⁴ Finally, states are limited in their ability to address surprise bills that involve an out-of-state provider, including an out-of-state provider of air ambulance services.

As states, the Federal Government, oversight agencies, and advocacy groups have examined the issue of air ambulance services and balance billing, it has become clear that there is a lack of comprehensive, national data on air ambulance costs, transports, and contractual arrangements between providers of air ambulance services and plans and issuers. In its 2017 report, the GAO recommended that the Federal Government assess available data to determine what additional information would be needed to address future concerns regarding unfair or deceptive practices.¹⁵ In addition, section 418 of the FAA Reauthorization Act of 2018 directed the Secretary of Transportation, in consultation with HHS, to form an Advisory Committee on Air Ambulance and Patient Billing (Advisory Committee). In January 2021, the Advisory Committee's subcommittee on the Prevention of Balance Billing recommended to the full Advisory Committee the collection of data to “(a) improve understanding of the air ambulance industry by policymakers, (b) increase transparency of market conditions impacting air ambulance services, and (c) indirectly improve contract negotiation between payors and air ambulance providers and suppliers.”¹⁶

provisions of 14 CFR part 298. See, for example, *Scarlett v. Air Methods Corp.*, 922 F.3d 1053 (10th Cir. 2019); *Air Evac EMS v. Cheatham*, 910 F.3d 751 (4th Cir. 2018).

¹³ See, for example, *Guardian Flight LLC v. Godfreed*, 991 F.3d 916, 921 (8th Cir. 2021) (holding that ADA preempted state law prohibiting out-of-network providers of air ambulance services from balance billing and requiring them to accept amounts paid by insurers); *Bailey v. Rocky Mountain Holdings, LLC*, 889 F.3d 1259, 1269–72 (11th Cir. 2018) (holding that ADA preempted state law that prohibited providers of air ambulance services from collecting more than amount specified in fee schedule).

¹⁴ In addition, FEHB contract terms preempt state law in accordance with 5 U.S.C. 8902(m)(1).

¹⁵ See *Air Ambulance: Data Collection and Transparency Needed to Enhance DOT Oversight*. GAO–17–637 (July 27, 2017).

¹⁶ Air Ambulance and Patient Billing Advisory Committee's Subcommittee on Prevention of

Section 106 of the No Surprises Act takes important steps to increase transparency regarding air ambulance services. Specifically, section 106(a) of the No Surprises Act requires providers of air ambulance services to submit certain data to the Secretaries of HHS and Transportation. Section 106(b) of the No Surprises Act requires plans and issuers to submit certain data on air ambulance services to the Secretaries of HHS, DOL, and the Treasury, through section 9823 of the Code, section 723 of ERISA and section 2799A–8 of the PHS Act. Section 106(d) of the No Surprises Act requires HHS, in consultation with the Secretary of Transportation, to specify through notice and comment rulemaking, the form and manner in which the reports described under section 106(a) of the No Surprises Act (regarding reporting by providers of air ambulance services) and section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act (regarding reporting by plans and issuers) must be submitted to such Secretaries. Therefore, in these proposed rules, HHS proposes amendments to 45 CFR part 149 that specify the form and manner of these reports. In addition, the Department of the Treasury and DOL propose to add 26 CFR 54.9823–1 and 29 CFR 2590.723 to specify that group health plans and health insurance issuers offering group health insurance coverage would satisfy the requirements under section 9823 of the Code and section 723 of ERISA, respectively, by submitting a report to HHS that satisfies the requirements of 45 CFR 149.230. In the interest of burden reduction and efficiency, the Departments propose that the required information reporting by group health plans and health insurance issuers offering group and individual health insurance coverage, together with the required information reporting by FEHB carriers,¹⁷ would be satisfied through reporting to HHS.

B. Basis and Scope (45 CFR 149.10)

HHS proposes to amend 45 CFR 149.10(a) to add a reference to section 106(a) of the No Surprises Act, which

Balance Billing, “A Report on the Prevention of Balance Billing”, January 2021, DOT–OST–2018–0206–0026_attachment_1. At its second full committee meeting in May 2021, the Advisory Committee recommended the collection of eight specific data elements from providers of air ambulance services. See section I.A of the preamble. The Committee's final report containing this recommendation had yet to be produced at the time this rulemaking was published.

¹⁷ OPM proposes to authorize and require FEHB carriers to submit air ambulance data to HHS. OPM will coordinate with HHS to receive FEHB air ambulance services data.

requires data reporting by providers of air ambulance services, to the basis of part 149.

C. Applicability (45 CFR 149.20)

HHS proposes to amend 45 CFR 149.20 to include a reference to the new subpart C, which under these proposed rules would include data submission requirements for plans and issuers. See section II.F. of the preamble for discussion of the applicability of the proposed rules regarding data submission requirements for providers of air ambulance services.

D. Definitions (45 CFR 149.30)

HHS proposes to amend 45 CFR 149.30 by adding definitions relevant to data submission requirements for providers of air ambulance services and plans and issuers. The Departments propose to define an air ambulance base as a site from which a provider of air ambulance services operates to provide air ambulance services. The Departments propose to define a National Provider Identifier (NPI) by referencing the definition in 45 CFR 162.406. The Departments seek comment on these proposed definitions.

E. Reporting Requirements for Plans and Issuers Regarding Air Ambulance Services (45 CFR 149.230)

HHS proposes to amend part 149 by adding 45 CFR 149.230 to subpart C to describe the data reporting requirements for plans and issuers. Proposed 45 CFR 149.230(a) includes general requirements, the timing and form of the data submission, and the reporting requirements in circumstances when a transfer of business occurs.

As discussed in sections I.A and II.A of the preamble, section 106(b) of the No Surprises Act added parallel provisions at section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act requiring plans and issuers to submit information regarding air ambulance services jointly to the Departments. Section 106(d) of the No Surprises Act directs HHS, in consultation with the Secretary of Transportation, to undertake notice and comment rulemaking to specify the form and manner in which plans and issuers must submit this information.

Therefore, in these proposed rules, HHS proposes amendments to 45 CFR part 149 that specify the form and manner for the reports required in section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act, as enacted in section 106(b) of the No Surprises Act. In the interest of burden reduction and efficiency, the Department of the Treasury and DOL

propose to add 26 CFR 54.9823–1 and 29 CFR 2590.723, respectively, to provide that plans and issuers would satisfy the requirements to submit information pursuant to section 9823 of the Code and section 723 of ERISA by satisfying the information reporting requirements under proposed 45 CFR 149.230. Similarly, as discussed further in section IV of the preamble, OPM proposes to add conforming reporting requirements to require FEHB carriers to comply with the requirements of proposed 45 CFR 149.230 with respect to an FEHB plan in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage.

The Departments interpret section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act to require plans and issuers to submit data regarding air ambulance services on a calendar year basis. The Departments are of the view that a calendar year reporting period would maximize the uniformity of the data across all submitters and provide a suitable basis for performing the trend analyses that section 106(c) of the No Surprises Act requires HHS to conduct as part of developing a comprehensive public report. In order to ensure completeness of the data, the Departments propose that data with respect to a calendar year would include both data relevant to air ambulance services furnished within the calendar year, as well as data relevant to services for which payments were made within the calendar year (even if the service was provided in a different calendar year). The Departments are of the view that this approach is necessary due to the limited duration of the data collection and statutory deadlines that may not allow sufficient time for claims run-out, particularly with respect to providers of air ambulance services that do not have contractual relationships with plans and issuers.

Based on the expectation that this rulemaking would be finalized during 2021, as required in section 106(d) of the No Surprises Act, and consistent with the statutory requirement on plans and issuers to report the required data not later than 90 days after the last day of the applicable calendar year, the Departments propose that plans and issuers would be required to submit the data for calendar year 2022 by March 31, 2023, and the data for calendar year 2023 by March 30, 2024. In order to ensure the completeness of the data, in proposed 45 CFR 149.230(a)(3), the Departments further propose that an issuer that acquires from another issuer

a line or block of business that provided coverage of air ambulance services during calendar years 2022 or 2023 would be required to report the air ambulance services data on behalf of the acquired business for the entire applicable calendar year. The Departments propose that these reporting requirements would apply to the selling and acquiring issuers if a sale or transfer occurs as a result of issuers being merged, combined, spun off, affected by, or engaging in any similar transaction during a calendar year. In addition, to ensure completeness and timeliness of reporting of all relevant air ambulance services data, the proposed rule would provide that the Secretary of HHS may provide examples of these transactions in guidance.

In addition, the Departments and OPM are publishing a proposed information collection, which would provide additional technical details regarding the required data elements, for public comment at the same time as or shortly after publishing these proposed rules. The proposed information collection would include a proposed data template and instructions. The proposed information collection would specify that plans and issuers do not need to submit information required in proposed 45 CFR 149.230 if they did not receive claims or make or expect to make payments for air ambulance services with respect to the reporting period.

Section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act require plans and issuers offering group or individual health insurance coverage to submit claims data for air ambulance services that include the following information about the claims: Whether the services were provided on an emergent or non-emergent basis; whether the provider of such services is part of a hospital-owned or sponsored program, municipality-sponsored program, hospital independent partnership (hybrid) program, independent program, or tribally operated program in Alaska; whether the transport originated in a rural or urban area; the type of aircraft used for the transport (fixed-wing or rotary-wing air ambulance); and whether the provider of the air ambulance service has a contract with the plan or issuer to provide air ambulance services.

Those statutory sections further require plans and issuers to provide, in addition to the information described in the preceding paragraph of the preamble, such other information regarding providers of air ambulance services as the Departments may

specify. Section 106(c) of the No Surprises Act requires HHS, in consultation with the Secretary of Transportation, to produce a comprehensive public report that must include several different analyses that require collection of other data not specifically identified in section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act. These analyses include: An assessment of the average charges for air ambulance services; amounts paid by plans and issuers to providers of air ambulance services; amounts paid out-of-pocket by consumers; the frequency of patient balance billing; the frequency of claims appeals made by providers of air ambulance services to plans and issuers; and any other data relating to air ambulance services determined necessary and appropriate by Secretaries of HHS and Transportation. To perform these analyses, the Secretaries of HHS and Transportation would need to be able to match the information collected from plans and issuers to the information collected from providers of air ambulance services under section 106(a) of the No Surprises Act.

Therefore, in proposed 45 CFR 149.230(b), HHS proposes to require submission of claims-level data on air ambulance services in order to collect the information necessary to satisfy these statutory requirements related to the HHS public report. Moreover, the Departments are of the view that submission of claims-level data would be less burdensome than submission of multiple sets of total claims data aggregated by the various categories described in section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act, particularly given the relatively small volume of claims for air ambulance services. It is the Departments' understanding that information regarding the service delivery model of the provider of air ambulance services (such as affiliation with a hospital or municipality or other similar program) may not be available to plans and issuers. Therefore, the Departments propose to require plans and issuers to report that data element only to the extent it is available to them.

The Departments appreciate the need to ensure both stakeholder and consumer privacy, particularly when collecting claims-level data, and therefore would take precautions to protect the confidentiality of claims-level data. HHS proposes to collect only that claims-level data that would be sufficient for producing the comprehensive report required by the statute. Moreover, HHS intends to

collect and maintain the information using information technology (IT) systems that are designed to meet all of the security standards protocols established under Federal law or by HHS relevant to such information.¹⁸

The claims-level data elements that HHS proposes to require plans and issuers to submit to support HHS's publication of the comprehensive public report, but that are not explicitly listed in section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act, include: The date of service; billing NPI and Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes information; and certain information about each air ambulance transport (such as the loaded miles and whether the transport was an inter-facility transport). These data elements, specifically the NPI and the date of service, would enable the Secretaries of HHS and Transportation to combine and validate the information collected from plans and issuers and the information collected from providers of air ambulance services.

Similarly, to enable the Secretaries of HHS and Transportation to analyze and summarize the data in an appropriate and meaningful manner in a comprehensive public report, HHS also proposes that the claims-level data elements include the market type of the plan or coverage associated with the air ambulance services. For fully-insured coverage, this would include the individual, small group, and large group markets, as defined in section 2791(e) of the PHS Act. For self-insured group health plans, this would include identification of the plan sponsor as a small employer or large employer, as defined in section 2791(e) of the PHS Act, with reasonable estimates allowed when the exact information on the size of the employer is not available. Under this proposal, FEHB plans would also be separately identified.

Further, to satisfy the requirements for the comprehensive public report described in section 106(c) of the No Surprises Act, including the required assessments of the frequency of patient balance billing and claims appeals made by air ambulance providers, HHS

proposes that the claims-level data elements include certain claim adjudication information (including whether the claim was paid, partially paid, denied, or appealed, and the reason for the denial and the outcome of the appeal, if applicable), as well as certain claim payment information (including submitted charges, amounts paid by the payor, and cost-sharing amount).

In order to streamline the provision of the required disclosures and to avoid unnecessary duplication of reporting with respect to group health insurance coverage, the Departments propose that, to the extent coverage under a plan consists of group health insurance coverage, the plan satisfies the reporting requirements if the plan requires the issuer offering the coverage to provide the information pursuant to a written agreement between the plan and the issuer. For example, if a plan and an issuer enter into a written agreement under which the issuer agrees to report the information required under proposed 45 CFR 149.230, and the issuer fails to submit a complete or timely report, then the issuer, but not the plan, would have violated these reporting requirements. However, if a plan has knowledge that the required report has not been submitted, the Departments would encourage the plan to work with the issuer to correct the noncompliance as soon as practicable or notify the applicable agency enforcing this requirement.

The Departments also highlight that nothing prevents a self-insured group health plan from contracting with another party, such as a third-party administrator (TPA), to report the required information, including, to the extent permitted under other Federal or state laws, entering into a written agreement for the other party to indemnify the plan in the event the other party fails to submit a complete or timely report. However, the plan would be required to monitor the other party to ensure that the entity is submitting the required information as it is ultimately the responsibility of the self-insured group health plan to report the information required under proposed 45 CFR 149.230. The proposed information collection instrument is designed in a manner that would enable a TPA that submits information on behalf of multiple self-insured group health plans to submit a single submission that includes the required data elements for all such plans.

Excepted benefits are exempt from requirements in chapter 100 of the Code, part 7 of ERISA, and Part A and

Part D of Title XXVII of the PHS Act.^{19 20} Short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and is exempt from the new requirements established in section 2799A–8 of the PHS Act. Therefore, short-term, limited-duration insurance (as defined in 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103) and coverage that consists solely of excepted benefits (as described in section 9832 of the Code, section 733 of ERISA, and section 2791 of the PHS Act) would not be subject to the reporting requirements set forth in 45 CFR 149.230 in these proposed rules. Individual coverage health reimbursement arrangements and other account-based plans, as described in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), make reimbursements subject to a maximum fixed dollar amount for a period, such that the benefit design of these coverage options makes concepts related to the reporting of data related to air ambulance services inapplicable. Therefore, under these proposed rules, the reporting requirements also would not apply to individual coverage health reimbursement arrangements and other account-based plans, consistent with the existing applicability provisions in 45 CFR 149.20 with respect to other No Surprises Act requirements in 45 CFR part 149.

Section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act (and other provisions of the No Surprises Act that are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage) apply to grandfathered health plans. Section 1251 of the Affordable Care Act provides that grandfathered health plans are not subject to certain provisions of the Code, ERISA, and the PHS Act, as added by the Affordable Care Act, for as long as they maintain their status as grandfathered health plans. For example, grandfathered health plans are subject neither to the requirement to cover certain preventive services without cost sharing under section 2713 of the PHS Act, nor to the annual limitation on cost sharing set forth

¹⁸ HHS's enterprise-wide information security and privacy program was launched in FY 2003, to help protect HHS against potential IT threats and vulnerabilities. The program ensures compliance with Federal mandates and legislation, including the Federal Information Security Management Act and the President's Management Agenda. The HHS Cybersecurity Program plays an important role in protecting HHS's ability to provide mission-critical operations. In addition, the HHS Cybersecurity Program is the cornerstone of the HHS IT Strategic Plan.

¹⁹ See section 9831 of the Code, section 732 of ERISA, and section 2722 of the PHS Act.

²⁰ The CAA amended the PHS Act statutory exemption for these products to include the new requirements established under the new Part D of the PHS Act. See section 102(a)(3)(B) of the No Surprises Act, which made conforming amendments to add the phrase "and Part D" to section 2722(b), (c)(1), (c)(2) and (c)(3) of the PHS Act.

under section 2707(b) of the PHS Act. If a plan or coverage were to lose its grandfathered status, it would be required to comply with both provisions, in addition to several other requirements. However, the CAA does not include an exception for grandfathered health plans that is comparable to section 1251 of the Affordable Care Act. Furthermore, section 102(d)(2) of the No Surprises Act amended section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protections provisions of the No Surprises Act, including those related to choice of health care professional, apply to grandfathered health plans. Therefore, the provisions of these proposed rules that apply to plans and issuers, proposed to be codified at 45 CFR 149.460, would apply to grandfathered plans.

The Departments seek comment on the use of the calendar year as the reporting period, including the time it typically takes to fully adjudicate and pay claims for air ambulance services (furnished by either participating or nonparticipating providers of air ambulance services), and the proposed data elements, as well as any potential challenges that plans and issuers may face in reporting the proposed data elements. The Departments also seek comment on the potential format for reporting the data.

F. Reporting Requirements Regarding Air Ambulance Services for Providers of Air Ambulance Services (45 CFR 149.460)

HHS proposes to amend 45 CFR part 149 by adding 45 CFR 149.460 to subpart E to describe the data reporting requirements for providers of air ambulance services. Proposed 45 CFR 149.460(a) includes the general requirements, the timing and form of the report, and the reporting requirements in circumstances where a transfer of business occurs. Proposed 45 CFR 149.460(b) outlines the information that would be required to be reported.

In proposed 45 CFR 149.460(a)(2), HHS interprets section 106(a) of the No Surprises Act to require providers of air ambulance services to submit data regarding air ambulance services on a calendar year basis, consistent with the proposal for the reporting period in proposed 45 CFR 149.230(a)(2). Moreover, typically, providers of air ambulance services do not operate based on plan years. HHS proposes that data with respect to a calendar year would include data relevant to air ambulance services furnished within the calendar year as well as data

relevant to services for which payments were made within the calendar year (even if the service was provided in a different calendar year). HHS expects that these proposed rules would be finalized during 2021, as required in section 106(d) of the No Surprises Act, and consistent with the requirement at section 106(a) of the No Surprises Act on providers of air ambulance services to report the required data not later than 90 days after the last day of the applicable calendar year. Thus, HHS proposes that providers of air ambulance services would be required to submit the data for calendar year 2022 by March 31, 2023, and submit the data for calendar year 2023 by March 30, 2024. In order to ensure completeness of the data, in proposed 45 CFR 149.460(a)(3), HHS further proposes that a provider of air ambulance services that acquires a line or block of business from another provider of air ambulance services that provided such services during calendar years 2022 or 2023 would be required to report the air ambulance services data on behalf of the acquired business for the entire applicable calendar year. The Departments propose that these reporting requirements would apply to the selling and acquiring providers of air ambulance services if a sale or transfer occurs as a result of providers of air ambulance services being merged, combined, spun off, affected by, or engaging in any similar transaction during a calendar year. In addition, to ensure completeness and timeliness of reporting of all relevant air ambulance services data, the proposed rule would provide that the Secretary of HHS may provide examples of these transactions in guidance.

Section 106(a) of the No Surprises Act requires providers of air ambulance services to submit the following information regarding air ambulance services: Cost data separated to the maximum extent possible by air transportation costs and costs of medical services and supplies associated with furnishing air ambulance services; the number and location of all air ambulance bases; the number and type of aircraft operated by the provider; the number of transports by payor mix (including plans, issuers, government payors, and the uninsured); the number of claims denied by group health plans or health insurance issuers and the reasons for denials; and the number of emergency and non-emergency transports by base and by type of aircraft.

Section 106(a) of the No Surprises Act further requires providers of air ambulance services to report, in

addition to the information described in the preceding paragraph, such other information regarding air ambulance services as the Secretaries of HHS and Transportation may specify. As noted in section II.E. of the preamble, section 106(c) of the No Surprises Act requires HHS to produce a comprehensive public report that must address several topics that require collection of additional information not specifically identified in section 106(a) of the No Surprises Act. These topics include: The percentage of providers of air ambulance services in various service delivery models (such as hospital-sponsored or municipality-sponsored programs); an assessment of the extent of competition among providers of air ambulance services on the basis of price and services offered; the average charges for air ambulance services; amounts paid by plans, issuers, and consumers; an assessment of the presence of air ambulance bases in, or with the capability to serve, rural areas and the relative growth in air ambulance bases in rural and urban areas over time; the percentage of providers of air ambulance services that have contracts with plans or issuers; unreasonable market concentration or excessive market domination that enable unreasonable price increases, and analyses of the debt collection practices against patients under various service delivery models; the frequency of patient balance billing, and the frequency of claims appeals made by providers of air ambulance services to plans and issuers; and any other data relating to air ambulance services determined necessary and appropriate by the Secretaries of HHS and Transportation. To address these topics, including performing the required analyses and assessments, HHS would need to be able to match the information collected from plans and issuers to the information collected from providers of air ambulance services.

Section 106(c)(2) of the No Surprises Act permits the Secretaries of HHS and Transportation to incorporate information from independent experts and third-party sources in the development of the report. HHS examined various sources of data and spoke with several industry experts and determined that in several areas, the data required to produce the analyses required in section 106(c)(1) of the No Surprises Act are not available from other sources. Therefore, in order to support the development of the report required in section 106(c)(1), HHS proposes collecting the necessary data from providers of air ambulance

services as described in these proposed rules. However, HHS seeks comment on additional data sources that may inform the development of the report, and the extent to which such data sources could be used in lieu of collecting specific data elements.

In proposed 45 CFR 149.460(b), HHS proposes requiring submission of air ambulance base-level and transport-level data on air ambulance services, as well as data elements not specifically identified in section 106(a) of the No Surprises Act, in order to collect the information necessary to satisfy these statutory requirements. For example, collection of data on revenue of the provider of air ambulance services from various sources, including non-transport sources, is necessary and appropriate to assess the competitiveness of the market for air ambulance services for purposes of the public report required under section 106(c) of the No Surprises Act, as well as to validate the data against the data collected from plans and issuers. Similarly, collection of air ambulance base-level data would help inform assessments regarding the competitiveness of the markets as well as capacity, service availability, and gaps in rural access to air ambulance services, which the Secretaries of HHS and Transportation are required to assess under section 106(c). Further, collection of transport-level data would enable the Secretaries of HHS and Transportation to conduct the assessments required under section 106(c) regarding the prices and services offered, the average charges for air ambulance services, and amounts paid by plans, issuers, and consumers, and would allow the Secretaries to complete the analyses of the debt collection practices, the frequency of patient balance billing, and the frequency of claims appeals.

Section 106(a)(2) of the No Surprises Act requires providers of air ambulance services to submit data on the number and location of all air ambulance bases they operate, the number and type of aircraft they operate, and the number of transports disaggregated by payor mix. In proposed 45 CFR 149.460(b)(2), HHS proposes collecting this information for each base, as well as additional information specific to the base and the aircraft that would enable the Secretaries of HHS and Transportation to conduct the assessments required in section 106(c) of the No Surprises Act. This additional information would include the NPIs associated with the base, the number and type of staff, the number and type of air ambulance transports per aircraft (including scene response patient transports, inter-

facility patient transports, and transports of organs, medical personnel, and medical supplies), and the number of air ambulance responses for the base, including the number of such responses that did not result in transports. The additional information would also include the service delivery model(s) of the base (a hospital-owned or sponsored program, municipality-sponsored program, hospital independent partnership (hybrid) program, independent program, or tribally operated program in Alaska) and whether the base shares operational costs with the affiliated or sponsor organizations, to complement and support the data required to be collected under section 9823(b)(1)(B) of the Code, section 723(b)(1)(B) of ERISA, section 2799A-8(b)(1)(B) of the PHS Act, and section 106(a)(2)(D) of the No Surprises Act. The rationale for collecting this additional information is that service delivery models may vary by air ambulance base in addition to by provider. The additional information would also include base-specific data related to the providers' of air ambulance services in-network contractual arrangements with plans and issuers as well as other, non-direct payor contracts with plans, issuers, or other entities (including, but not limited to, TPAs or provider networks). This additional information would complement and support required data submissions and would also include air medical subscriptions or ambulance/emergency medical service membership programs associated with the base, and whether the base operates ground ambulance services in addition to air ambulance services. Finally, collection of this additional information would enable analyses under various provisions of section 106(c)(1) of the No Surprises Act.

Section 106(a) of the No Surprises Act requires providers of air ambulance services to submit cost data for air ambulance services, as HHS determines appropriate, and section 106(a) requires providers of air ambulance services to separate, to the maximum extent possible, air transportation costs and the costs of medical services and supplies. HHS reviewed the ambulance cost reporting forms developed for the Medicare Ground Ambulance Data Collection System, ambulance cost reporting forms developed by states, a cost report study prepared for the Association of Air Medical Services and Members, a review of several studies on air ambulances services, consulted with the Secretary of Transportation and subject matter experts, and held

listening sessions and additional conversations with providers of air ambulance services. Based on these activities, HHS determined that the service delivery or organizational model of a provider of air ambulance services, the designation of the service area of a base (rural or urban),²¹ and the identification of fixed and variable costs are all important factors affecting the costs and revenues of providers of air ambulance services. Because these factors vary at the air ambulance base level, HHS proposes in 45 CFR 149.460(b) to require submission of detailed cost and revenue data at the air ambulance base level, as well as at the regional and corporate level, for each air ambulance base, if applicable. The data HHS proposes to collect would enable the separation of fixed and variable costs of providers of air ambulance services, as well as medical costs as opposed to air transportation costs.

HHS proposes in 45 CFR 149.460(b)(3) that the required cost data be reported in the following categories: Labor costs by type of staff; facility costs by facility (including annual lease, rental, or mortgage costs, other costs of ownership, insurance, maintenance and improvements, utilities, taxes, computers and software, and other facility costs); vehicle costs by vehicle (including vendor fees, depreciation, safety enhancements, non-medical equipment (such as communications technology), registration and license, taxes, insurance, maintenance equipment and parts, fuel, and capital medical equipment); equipment and supplies; and overhead and vendor costs (including insurance, training, billing, accounting and finance, human resources, travel, marketing, sales, dispatch or call center, IT support, legal, medical direction, fees, fines, and taxes).

HHS proposes in 45 CFR 149.460(b)(4) that the required revenue data would include: Total revenue from paid air ambulance transports, by payor type, as well as revenue from other sources (such as contracts with facilities such as hospitals, prisons, and nursing homes); revenue from emergency air medical services other than for transports (for example, for transportation of organs, medical personnel, supplies, or equipment on an

²¹ HHS may apply a custom definition or a broadly accepted definition, such as the one used by CMS for the Medicare Ambulance Fee Schedule, to determine whether air ambulance bases and services are provided in rural or urban areas. More detail on the Medicare Ambulance Fee Schedule is available at: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/ambulancefee-schedule>.

emergency basis); revenue from sub-contracted ambulance services; fees for standby events; payments from non-contract contracts such as waiver, rental, lease, and supplemental arrangements; air medical subscriptions and ambulance or emergency medical service membership programs; charitable donations and foundation funding; program-related investments; receipt of local taxes earmarked for emergency medical services; contract revenues from local governments in return for air ambulance services; enterprise funds and utility rates; sales of assets and services; bond or debt financing; state or local donation of vehicles or durable equipment; and funding grants or the provision of time-limited funding from a government entity (including Federal, state, local, or other). The revenue data would enable the Secretaries of HHS and Transportation to conduct the holistic assessments required in various provisions of section 106(c)(1) of the No Surprises Act, including with respect to the ability of providers of air ambulance services to compete on the basis of price and services in various geographic areas, these providers' financial capability to serve rural areas, the relationship of the average charges for air ambulance services to business costs and market dynamics and characteristics, potential anti-competitive behaviors by providers of air ambulance services, and other factors that may affect the costs of air ambulance services.

Finally, section 106(a)(2) of the No Surprises Act requires providers of air ambulance services to submit the following data regarding air ambulance transports: The number of transports by payor mix (group health plans, health insurance issuers, state and Federal Government payors, and the uninsured); the number of claims for air ambulance services that have been denied payment by plans or issuers and the reasons for such denials; and the number of emergent and non-emergent transports disaggregated by air ambulance base and type of aircraft. In 45 CFR 149.460(b)(5), HHS proposes to require submission of transport-level data on air ambulance services in order to satisfy these statutory reporting requirements, as well as to collect the data necessary to enable HHS, in consultation with the Secretary of Transportation, to conduct the assessments required in section 106(c) of the No Surprises Act.

The transport-level data elements in addition to those specifically identified in section 106(a) of the No Surprises Act that HHS proposes to collect from providers of air ambulance services

include: Date of service; billing NPI and CPT/HCPCS codes information; and certain information about the transport (such as the air ambulance base, flight duration, loaded miles, pick-up (origin) and drop-off (destination) locations and the point of ambulance pick-up zip code, and whether the transport was a scene response patient transport, inter-facility patient transport, or other transport (such as organ, medical personnel, or medical supplies transport)). These data elements would enable the Secretaries of HHS and Transportation to identify, combine, and validate the information collected from plans and issuers, and the information collected from providers of air ambulance services, as well as evaluate potential gaps in rural access.

Consistent with the requirements in section 106(a) of the No Surprises Act and to enable HHS to combine and validate the information collected from providers of air ambulance services under these proposed rules with air ambulance data from other sources, as well as to enable HHS to assess abusive patient collection practices across various payors as required in section 106(c)(1)(I) of the No Surprises Act, HHS proposes requiring identification of the primary payor type for each transport, such as Medicare fee-for-service (FFS), Medicare Advantage, Medicaid, Veterans' Health Administration, TRICARE, Indian Health Service, group health plan, health insurance issuer, FEHB plan, Workers' Compensation, patient cost-sharing, and patient self-pay. Further, to satisfy the requirements for the comprehensive public report described in section 106(c) of the No Surprises Act, HHS proposes that the transport-level data elements should include information regarding the contractual arrangement with the plan or issuer, if applicable, to furnish air ambulance services under the plan or coverage, respectively, to support the assessment required in section 106(c)(1)(F) of the No Surprises Act, as well as the payment methodology for the transport (such as the base rate, mileage, and intervention or other charges), if applicable, as recommended by experts. For the same reasons, HHS proposes that the transport-level data elements should also include: Certain claim adjudication information (including whether the claim was paid, denied, or appealed, and the reason for the denial or the outcome of the appeal, if applicable) to support the data collection and analyses required in sections 106(a)(2)(E) and (c)(1)(J) of the No Surprises Act; certain payment

information (including submitted charges, amounts paid by the payor not including the patient, and cost-sharing amount (if applicable)) to support the assessment required in section 106(c)(1)(C) of the No Surprises Act; the amount billed to the patient, the amount collected from the patient, and whether the bill was referred for collection, including lawsuits, liens, or wage garnishment actions to support the assessments required in section 106(c)(1)(G) and (c)(1)(I) of the No Surprises Act; and information on any payments from sources other than the primary payor, such as membership fees and state or municipal subsidies to support the analyses required in section 106(c)(1)(B), (c)(1)(H), and (c)(1)(K) of the No Surprises Act.

In order to protect stakeholder and consumer privacy, particularly when collecting transport-level data, HHS would take precautions to protect the confidentiality of transport-level data. HHS proposes to collect only that transport-level data that would be sufficient for producing the comprehensive report required by the statute. HHS intends to collect and maintain the information using information technology (IT) systems that are designed to meet all of the security standard protocols established under Federal law or by HHS relevant to such information.

HHS is publishing the proposed information collection for public comment at the same time as or shortly after these proposed rules. The proposed information collection would include a proposed data template and instructions.

HHS seeks comment on the use of the calendar year as the reporting period, including the time it typically takes payors to fully adjudicate and pay claims for air ambulance services (furnished by either participating or nonparticipating providers of air ambulance services), the proposed data elements described in this section of the preamble, the appropriate levels for reporting of these data elements (regional/corporate, base, transport), and potential challenges that providers of air ambulance services may face in reporting the proposed data elements, including any special considerations for the reporting of the proposed data elements with respect to municipality and other government-owned or sponsored providers of air ambulance services. HHS also seeks comment on the potential format for reporting the data.

III. Provisions of the Proposed Rules— Department of HHS

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Basis and Purpose (45 CFR 144.101)

HHS proposes conforming amendments to 45 CFR 144.101 to reflect the proposed amendments to 45 CFR part 150, described in section III.C of the preamble. Specifically, HHS proposes to revise 45 CFR 144.101(e)²² to include references to the enforcement-related provisions added by the No Surprises Act (section 2799B-4 of the PHS Act and section 106(e) of the No Surprises Act), and to specify that the enforcement provisions in 45 CFR part 150 apply to the provisions of 45 CFR part 149 concerning group or individual health insurance, providers and facilities, and providers of air ambulance services.

B. Part 148—Requirements for the Individual Health Insurance Market

1. Authority

HHS proposes to make technical corrections to the authority listed for 45 CFR part 148. More specifically, HHS proposes to update the list to reference the Federal insurance reforms applicable to the individual market captured in PHS Act sections 2722 through 2763, codified at 42 U.S.C. 300gg-21 through 300gg-63, along with PHS Act sections 2791 and 2792, codified at 42 U.S.C. 300gg-91 and 300gg-92. This would include new section 2746 of the PHS Act, as added by section 202(c) of Title II of Division BB of the CAA, in the list of authorities for 45 CFR part 148. Finally, HHS proposes to remove the reference to PHS Act section 2711, codified at 42 U.S.C. 300gg-11, because this statutory provision is not implemented as part of the HHS regulations in 45 CFR part 148.²³

2. Basis and Purpose (45 CFR 148.101)

HHS proposes to amend 45 CFR 148.101 to expand the purpose of 45 CFR part 148. Specifically, HHS proposes to add a reference to the new reporting and disclosure requirements

²² The July 2021 interim final rules redesignated paragraph (d) of 45 CFR 144.101 as paragraph (e) and further redesignated paragraph (e) of 45 CFR 144.101 as paragraph (f). Although the effective date of the July 2021 interim final rules is not until September 13, 2021, references to paragraph (e) in these proposed rules are references to the newly redesignated paragraph (e) (formerly paragraph (d)). This rule also proposes a technical correction to 45 CFR 144.103(e)(2) to correct a cross-reference that was inadvertently not updated when paragraph (d) was redesignated.

²³ See 45 CFR 147.126. Also see 45 CFR 146.123.

regarding agent and broker compensation that these proposed rules would add as a new subpart F to 45 CFR part 148 to implement the requirements of section 2746 of the PHS Act, as added by section 202(c) of Title II of Division BB of the CAA.

3. Scope and Applicability Date (45 CFR 148.102)

HHS proposes to amend 45 CFR 148.102 by adding paragraph (a)(3) to specify that the requirements in proposed 45 CFR 148.410 would apply to health insurance issuers of individual health insurance coverage and short-term, limited-duration insurance. HHS also proposes to amend paragraph (b) by excepting 45 CFR 148.410 from the applicability dates specified in paragraph (b), as these proposed rules set forth the applicability date specific to 45 CFR 148.410 in that section.

Section 2746 of the PHS Act, as added by section 202(c) of Title II of Division BB of the CAA, applies to grandfathered individual health insurance coverage, for the reasons set forth in section II.E of the preamble. Therefore, the provisions in proposed 45 CFR 148.410 that apply to individual health insurance coverage, would apply to grandfathered as well as nongrandfathered individual health insurance coverage.

4. Subpart F—Requirements Related to Reporting and Disclosure

HHS proposes to add a new subpart F to 45 CFR part 148 and new 45 CFR 148.410 within that subpart to implement the requirements of section 2746 of the PHS Act, as added by section 202(c) of Title II of Division BB of the CAA. Section 2746 of the PHS Act requires health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to make disclosures to enrollees and submit reports to HHS regarding direct and indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage. Sections 2746(b) and (c) of the PHS Act detail the specific requirements for disclosure and reporting, respectively. HHS proposes to codify these requirements in new proposed 45 CFR 148.410.

Agents and brokers enter into appointment arrangements with health insurance issuers; these arrangements, which are generally regulated by state law, govern compensation provided to agents and brokers for assisting consumer enrollment in an issuer's plans. The specific compensation arrangement between a health insurance

issuer and the agent or broker is typically laid out in a written document such as a commission schedule.

Compensation arrangements may also include other types of compensation, such as fees and bonuses. Section 2746 of the PHS Act improves the transparency of this compensation system by requiring the disclosure of this compensation information to consumers and reporting of this information to HHS.

5. Subpart F—Requirements Related to Reporting and Disclosure—Disclosure of Agent and Broker Compensation to Individuals in Individual Health Insurance Coverage or Short-Term, Limited-Duration Insurance (45 CFR 148.410)

a. Health Insurance Issuer Standards

HHS proposes to add, in 45 CFR 148.410(a), a general statement of the obligations of health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance, to disclose to policyholders and report to HHS on an annual basis direct and indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage.

HHS proposes to add, in 45 CFR 148.410(b), definitions of key terms in these proposed rules. HHS proposes to define “agent or broker” through a cross-reference to the definition for the term in 45 CFR 155.20. Section 2746 of the PHS Act applies to both direct and indirect compensation paid to an agent or broker by a health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance, but does not define direct and indirect compensation. Therefore, HHS proposes regulatory definitions for these key terms that define direct and indirect compensation in a manner that covers all forms of consideration that might be transferred between an issuer offering individual health insurance coverage or short-term, limited-duration insurance and an agent or broker for enrollment in such coverage, regardless of the method by which that consideration is transferred.

In new proposed 45 CFR 148.410(b)(3), direct compensation is defined as monetary amounts, including sales and base commissions, paid by an issuer that are attributable directly to the policy, certificate, or contract of insurance and that are paid to an agent or broker for the sale, placement, or renewal of individual health insurance coverage or short-term, limited-duration insurance. HHS proposes in new proposed 45 CFR 148.410(b)(4) to define

indirect compensation as payments by an issuer attributable indirectly to a policy, certificate, or contract of insurance to agents, brokers, and other persons for items other than sales and base commission. Examples of indirect compensation include service fees, consulting fees, finders' fees, profitability and persistency bonuses, awards, prizes, volume-based incentives, and non-monetary forms of compensation. HHS proposes in new proposed 45 CFR 148.410(b)(2) to define a commission schedule as an itemized list or table that provides the commission levels that are paid by an issuer for the sale, placement, or renewal of individual health insurance coverage or short-term, limited-duration insurance. These definitions are based on the most common and essential terms HHS has observed in various examples of issuer commission schedules in the individual market. HHS proposes to define policyholder in new proposed 45 CFR 148.410(b)(5) for purposes of this section as the individual who purchases individual health insurance coverage or short-term, limited-duration insurance and is responsible for the payment of premiums.

b. Disclosure Requirements

To ensure transparency of agent and broker compensation when purchasing individual health insurance coverage or short-term, limited-duration insurance, and to implement sections 2746(b)(1) and (2) of the PHS Act, HHS proposes in new proposed 45 CFR 148.410(c) to codify the requirement that health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance must disclose to a potential or existing policyholder the amount of direct and indirect compensation provided to an agent or broker associated with enrolling the policyholder in the individual health insurance coverage or short-term, limited-duration insurance. This disclosure would be required to include the commission schedule used to determine the compensation owed to an agent or broker as part of the appointment contract between the agent or broker and the health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance, as well as the structure for compensation not captured on the commission schedule.

Consistent with the requirements in section 2746(b) of the PHS Act, HHS proposes in new proposed 45 CFR 148.410(c)(2) that for new, initial enrollments, this disclosure would be required to be made prior to when

potential policyholders finalize plan selection and also to be included on any documentation confirming the initial enrollment, including enrollment documentation required in applicable state or Federal law or an initial enrollment package. Section 2746(b)(2) of the PHS Act requires health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to include the disclosure on any documentation confirming the individual's enrollment. HHS recognizes that the term "any documentation" could be read broadly to refer to any documentation that a health insurance issuer provides during a plan year that serves as confirmation that the individual is enrolled in the coverage. However, HHS is of the view that requiring such a broad reading of the statutory requirement would be burdensome to issuers, without producing a commensurate benefit to individuals who receive the disclosure. Therefore, HHS proposes to interpret the statutory language more narrowly. Specifically, with respect to initial enrollments, HHS proposes, in 45 CFR 148.410(c)(2), to require disclosure on any documentation confirming initial enrollment, including enrollment documentation required in applicable state or Federal law or an initial enrollment package.²⁴ In addition, consistent with the provisions in section 2746(d) of the PHS Act that recognize the need to account for the different processes for plan renewals, HHS proposes in new proposed 45 CFR 148.410(c)(3) that for renewals of enrollment in a plan, an issuer must provide the required disclosure to the policyholder with the renewal notice required in 45 CFR 147.106(f) or 148.122(i), if applicable. HHS proposes this because plan renewals in the individual market generally do not have a moment when a consumer finalizes plan selection, as many of these renewals occur automatically, and because these renewal notices can also be considered to confirm enrollment in the plan for the upcoming plan year. Therefore, issuers would be required to provide the required disclosure as part of an initial enrollment package or renewal notice, but would not be required to provide the required disclosure on other documents that could be considered to confirm

²⁴ For example, pursuant to 45 CFR 147.200(a)(1)(iv), a health insurance issuer offering individual health insurance coverage must provide a summary of benefits and coverage to an individual covered under the policy upon application, by the first day of coverage (if there are changes), upon renewal, reissuance, or reenrollment, and upon request.

enrollment, such as explanations of benefits.

In the absence of any documentation required by applicable state or Federal law to confirm initial enrollment, or the requirement for a notice of renewal of coverage with respect to short-term, limited-duration insurance, HHS proposes, as a default in new proposed 45 CFR 148.410(c)(4), that issuers would be required to provide the disclosure with the invoice for the first premium payment for the initial coverage term and for each renewal period. HHS invites comment on whether there are other forms of documentation confirming enrollment for either individual health insurance coverage or short-term, limited-duration insurance on which disclosure of compensation information should be required and whether requiring delivery of the disclosure at another time, such as between the final plan selection and issuance of the invoice for the first premium payment, may be more appropriate.

HHS proposes to codify in new proposed 45 CFR 148.410(c)(5) minimum requirements for disclosure of direct and indirect compensation information. HHS proposes that, at a minimum, a health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance could satisfy the disclosure requirement using the commission schedules or other documents that detail the applicable commission levels and indirect compensation, such as bonuses. When used to satisfy this new disclosure requirement, these documents must clearly specify commissions paid by an issuer to an agent or broker for the applicable plans for which the agent or broker has an appointment arrangement with the issuer, distinguish between commission payments for new enrollments and such payments for renewed enrollments if the issuer differentiates compensation for those two types of enrollment, and explain the qualifying thresholds for the payment of indirect compensation to an agent or broker. Requiring that the disclosure must include a commission schedule would ensure a consistent and readily available document for all policyholders to use to understand the compensation that their insurance agent or broker would receive and make informed purchasing decisions. If an issuer of individual health insurance coverage or short-term, limited-duration insurance also offers direct or indirect compensation that is not captured by the commission schedule, the issuer must supplement the disclosure of the information on the commission

schedule with additional documentation disclosing such other compensation.

HHS expects that issuers subject to the requirements of this section would integrate this new disclosure requirement into their existing compliance operations. An issuer's obligation could be satisfied by the agent or broker making the required disclosure on the issuer's behalf. For example, issuers may provide agents or brokers who have an appointment arrangement with the issuer printed versions of the commission schedule and other documentation disclosing direct and indirect compensation, if applicable, to attach to enrollment materials or may provide a link to an online version of the document. This would equip agents and brokers with the information necessary to ensure that consumers would be aware of any compensation being paid by the issuer to the agent or broker prior to enrolling. Whether issuers choose to comply directly with this obligation or partner with their agents and brokers to provide the required disclosure, materials provided would be required to be made available in accessible formats for people with disabilities (at no cost to the individual) and people with limited English proficiency. Issuers would be required to comply with applicable Federal language and accessibility requirements regarding disclosure documents.²⁵ This typically requires documents to be made available in any of the 15 most common languages in the state.²⁶ Issuers would also be required 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. Information provided through information and communication technology also must be

accessible to individuals with disabilities, unless certain exceptions apply.²⁷ HHS is of the view that individuals cannot receive meaningful disclosure if they cannot understand the information provided in the disclosure documents. HHS seeks comment on these proposals.

These proposed rules do not prescribe a specific format for issuers' commission schedules or other documents that detail the applicable direct or indirect compensation. Instead, HHS proposes in 45 CFR 148.410(c)(5) that, to the extent the commission schedules or other documents that detail the applicable direct or indirect compensation are used to satisfy the requirements of this section, the schedules or other documents would be required to comply with the minimum standards outlined therein regarding agent and broker compensation. This proposed requisite information includes information on initial and renewal commissions and explanation of the qualifying thresholds for the payment of indirect compensation to an agent and broker, at a minimum. Commission schedules are widely used in the health insurance industry and customarily include this minimum informational content with respect to initial and renewal commission rates. However, the format can vary by issuer. It is HHS's view, at this time, that the benefits of prescribing and standardizing the proposed minimum required content in a specific format for commission schedules would not outweigh the costs of implementation. HHS is also not proposing a specific format for the additional documentation that detail the applicable direct or indirect compensation. Instead, HHS is proposing minimum standards for the information that must be disclosed and permitting issuers to determine what documentation may contain that information and be used to satisfy the disclosure requirement, whether the issuer calls it a commission schedule or refers to it by another term. HHS invites comments on these proposals, especially the considerations of costs and benefits associated with standardizing the format for compensation disclosure.

HHS proposes that issuers would be required to make the necessary disclosures prior to the potential policyholder finalizing plan selection and, in addition, that the disclosure be included on any documentation confirming the individual's enrollment, as required under section 2746(b) of the

PHS Act. This requirement would ensure that the person who is choosing the coverage and agreeing to be financially responsible for premiums and other payments due under the insurance contract (who HHS proposes to define as the 'policyholder') can evaluate whether and to what extent the advice they received from an agent or broker may be influenced by the agent's or broker's compensation arrangement with an issuer prior to finalizing the plan selection.

HHS considered whether to propose requiring that issuers make these required disclosures to all plan enrollees, but are of the view that such a requirement would be needlessly burdensome. First, requiring issuers to disclose direct and indirect agent or broker compensation to each person in an enrollment group would be unreasonable as many enrollees are infants, minor children, or otherwise not responsible for choosing their health insurance coverage. As noted, requiring the disclosure be made to the policyholder would allow that individual to evaluate whether and to what extent the advice they received from an agent or broker may be influenced by the compensation received. HHS expects that the policyholder would be able to relay information from the disclosure to the other enrollees on the policy, similar to how the policyholder is entrusted to relay other information about the plan selection to the other enrollees in the policy. HHS is also of the view that requiring issuers to make these disclosures to each enrollee could place a larger burden on issuers and enrollees than necessary without adding meaningful consumer benefit. For example, to the extent an issuer uses the agent or broker to provide the disclosure, requiring disclosure to be made to all enrollees prior to finalizing the plan selection would necessitate an adult, seeking to purchase coverage for their family, to bring that entire family to the office of the insurance agent or broker in order to receive the disclosure of information about direct and indirect compensation before finalizing the plan selection in which the family members would be enrolled.

A similar burden exists for virtual or telephonic enrollments. The agent or broker assisting with the enrollment would need to contact each individual on the plan prior to finalizing plan selection, which could be time-consuming or nigh impossible. This would require all plan enrollees to be near a phone or computer at the time of enrollment and either answer a phone call or respond to an email prior to

²⁵ See, for example, Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250 (March 30, 2016) <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf> and "Appendix A—Top 15 Non-English Languages by State" https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Appendix-A-Top-15-non-english-by-state-MM-508_update12-20-16.pdf. See also 42 U.S.C. 18116, 42 U.S.C. 2000d *et seq.*, 269 U.S.C. 794, 42 U.S.C. 12101 *et seq.*

²⁶ *Ibid.*

²⁷ See 42 U.S.C. 18116, 42 U.S.C. 2000d *et seq.*, 269 U.S.C. 794, 42 U.S.C. 12101 *et seq.*

finalizing plan selection. This amount of coordination seems unduly burdensome on consumers and would virtually eliminate parents' ability to finalize a plan selection while their children are in school, as the children would generally be unable to be contacted by the agent or broker while attending classes. In addition, emails or phone calls from unknown individuals are often not answered or responded to promptly, if at all, meaning a policyholder would need to first contact the other plan enrollees, telling them to expect a call from the agent or broker, which adds another layer of coordination and complexity. Additionally, children or developmentally challenged individuals may not be mentally capable of providing their consent or may not have an email address or phone number, meaning if they were not physically with the policyholder at the time directly prior to finalizing plan selection, contacting them would be impossible.

c. Reporting Requirements

To implement the requirement at section 2746(c) of the PHS Act that health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance must annually report to HHS prior to the beginning of open enrollment any direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage, HHS proposes in new proposed 45 CFR 148.410(d)(1) to require issuers to submit to HHS, in a form and manner prescribed by the Secretary, any direct and indirect compensation provided to agents and brokers associated with enrolling individuals in individual health insurance coverage and short-term, limited-duration insurance sold by the issuer. HHS intends to collect data similar to the data collected by DOL on compensation of insurance producers for group health plans subject to the Form 5500 reporting requirement.

DOL utilizes the Form 5500 series as part of its overall reporting and disclosure under ERISA. DOL collects information related to insurance on Form 5500 Schedule A, which includes the identifying information for the issuer and the agent or broker, and the amount of compensation paid to agents and brokers. Issuers would be expected to submit the reporting data to HHS through an online system. HHS is proposing to require issuers provide, for each payment recipient and intermediary organization in a specific month of the reporting year, a single

row of data in comma-separated values (CSV) format containing the following fields/columns: (1) Payor Federal Tax ID Number (FTIN); (2) Recipient Identifier Type ("NPN" for writing agents or "FTIN" for payments made to intermediaries); (3) Recipient Identifier Value (the actual number); (4) The date on which the payment was made to the payment recipient; (5) Direct Compensation, expressed as a dollar amount (the commission); (6) Indirect Compensation, expressed as a dollar amount, if any (if indirect compensation payment amount was made in that month, for example, a bonus was paid out; bonuses for annual performance are accounted for in December of the reporting year rather than disaggregated into 12 parts for each month); (7) the basis for indirect compensation—a text field allowing entry of what the grounds for the indirect compensation were (bonus, incentive, etc.); and (8) other information specified by the Secretary, which may include, for example, distinguishing between individual health insurance coverage and short-term, limited-duration insurance, listing the appointment arrangement duration, and providing the number of plans the agent sold.

HHS proposes to add new proposed 45 CFR 148.410(d)(2) to specify that the reporting by issuers would be required to reflect both compensation arrangements directly between the writing agent or broker and the issuer, and compensation arrangements from the issuer to the writing agent or broker involving one or more intermediary organizations in connection with the sale of individual health insurance coverage or short-term, limited-duration insurance. Examples of intermediary organizations that are often involved in the sale, placement, or renewal of individual health insurance coverage or short-term, limited-duration insurance include general line agencies and marketing organizations. This proposed approach would ensure that the information reported annually to HHS reflects the full amount of compensation received by agents and brokers related to the sale, placement, or renewal of individual health insurance coverage and short-term, limited-duration insurance.

HHS proposes that the annual report submitted by issuers to HHS contain more detailed information than the disclosure to policyholders, including information related to intermediary organizations as well as actual compensation amounts rather than payment structures, because HHS proposes for the report to be due after the end of the year for which

compensation was paid and prior to the beginning of open enrollment for the following year. This timeline would enable the report to HHS to provide a more complete reflection of compensation actually provided throughout the previous calendar year than the disclosure to consumers, which must be provided prior to individuals finalizing their plan selections and at renewal. In addition, requiring issuers to provide information to policyholders on the compensation arrangements between insurance agents or brokers and intermediary organizations, like general agencies, would substantially increase the complexity of the disclosure materials without providing the same level of consumer benefit. Disclosure of direct and indirect compensation is intended to inform the consumer of considerations, other than the consumer's best interests, that may impact the guidance and decision-making of the insurance agent or broker. HHS is of the view that information about whether that compensation would first be paid to a general agency and the amount of compensation that agency would claim before disbursing to the agent would not have a similar impact on the consumer's decision-making process. However, reporting of this additional information to HHS would assist HHS in monitoring and enforcing compliance with the disclosure requirements and ensuring that consumer disclosures accurately and adequately reflect direct or indirect compensation payment practices.

HHS proposes in new proposed 45 CFR 148.410(d)(4) to require submission to HHS of the required reports on an annual basis by the last business day of July of the calendar year following the applicable reporting period. For example, reporting for calendar year 2022 would be due by July 31, 2023. Under this proposed rule, for non-calendar year policies, which may exist in the short-term, limited-duration insurance market, issuers would be required to split the agent and broker compensation between the reports for two calendar years. For example, for a short-term, limited-duration policy in effect from December 1, 2022 to February 28, 2023, an issuer would be required to report the compensation paid on the policy for December 2022 in the report due by July 31, 2023 and the compensation paid on the policy for January and February 2023 in the report due July 31, 2024. HHS seeks comment on this proposal, and would provide additional guidance in the final rule on special cases, as may be necessary, including indirect compensation paid

for enrollments that span multiple years based on comments on this proposed rule and feedback from regulated entities subject to these requirements and other stakeholders.

Section 2746(c) of the PHS Act states that issuers must report the data to HHS prior to the beginning of open enrollment. The last business day of July would align with the statute and would avoid significant overlap with the qualified health plan certification process and states' rate and form review processes. This date would also provide HHS with adequate time to review the submitted reports prior to the beginning of open enrollment for the following year and would provide issuers ample time after the reporting year to prepare and validate the information.

d. Applicability

In new proposed 45 CFR 148.410(e), HHS is proposing to codify the provisions of section 2746(d) of the PHS Act, which establishes a transition rule for these new requirements and provides that the requirements would not be applicable to contracts executed between health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance and agents or brokers before December 27, 2021. HHS therefore proposes that these new requirements would apply to contracts executed between an agent or broker and a health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance on or after December 27, 2021. For purposes of determining the date of contract execution, HHS proposes to deem the execution of contractual addenda or revisions to the material terms of a pre-existing contract to be the execution of a new contract to which the disclosure and reporting requirements would apply.

HHS does not expect that many appointment contracts would be newly executed between the effective date of the statutory requirement, December 27, 2021, and the beginning of the first reporting period proposed in these proposed rules, January 1, 2022. As a result, under this proposal, HHS may exercise discretion and adopt a temporary policy of relaxed enforcement in connection with the enforcement of the proposed reporting requirement on a case-by-case basis for appointment contracts executed and policies effective within the period between December 27, 2021 and January 1, 2022, and encourages states that are the primary enforcers of these requirements to adopt a similar enforcement approach.

HHS seeks comment on all aspects of these proposals regarding the definitions, disclosure requirements, reporting requirements, and applicability.

C. Part 150—CMS Enforcement of Group and Individual Insurance Market and Provider and Facility Requirements

Section 2723 of the PHS Act contemplates that states would exercise primary enforcement authority with respect to issuers that offer health insurance coverage in the individual or group markets within the state. If a state notifies HHS that it does not have the authority to enforce PHS Act requirements, or if HHS determines that a state is not substantially enforcing PHS Act requirements with respect to issuers, HHS has the responsibility to enforce the PHS Act provision or provisions in that state and has delegated this enforcement authority to CMS.

The CAA enacted new provisions of the PHS Act that require health insurance issuers to submit certain information to HHS or the Departments. This includes the requirement under section 2746(c) for issuers that offer individual health insurance coverage and issuers that offer short-term, limited-duration insurance coverage to annually report to the Secretary of HHS, prior to the beginning of open enrollment, any direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage. Health insurance issuers must also report to the Departments certain information regarding air ambulance services under section 2799A–8 and certain information regarding pharmacy benefits and drug costs under section 2799A–10. Additionally, in accordance with section 2799A–9(a)(4), issuers must submit to HHS an annual attestation of compliance with the prohibition of gag clauses on price and quality information under section 2799A–9. Under section 2723 of the PHS Act, states have the opportunity to be the primary enforcers of sections 2746(c), 2799A–8, 2799A–9(a)(4), and 2799A–10. However, HHS is of the view that states would not look to enforce these PHS Act provisions because they are requirements for issuers to report to HHS or the Departments, and states would not have access to the submissions to assess compliance. Instead, HHS anticipates that states would focus resources on implementing and enforcing the other requirements in the CAA. HHS therefore proposes to have direct enforcement authority for these issuer requirements in all states,

unless the state notifies HHS of its intent to enforce. HHS solicits comments on this approach and whether there are states that intend to assist with enforcement of any of these requirements.

In cases where there is a question about whether the state is failing to substantially enforce one or more PHS Act requirements, the procedures outlined in 45 CFR 150.201 through 150.221 govern. First, if CMS is satisfied that there is a reasonable question whether there has been a failure to substantially enforce one or more PHS Act requirements, CMS notifies the appropriate state parties, providing 30 days to respond. Then, if CMS makes a preliminary determination that the state is failing to substantially enforce, the state is provided an opportunity to show evidence of substantial enforcement. If CMS determines that the state's failure to substantially enforce has not been corrected, then CMS would send a final determination notice to the state identifying which requirements CMS would directly enforce and the effective date for such enforcement. Finally, current regulations provide a transition mechanism by which a state can assume or resume primary enforcement of the applicable PHS Act requirement(s).

Most states currently work to ensure that issuers offering health insurance coverage in the individual and group markets comply with applicable requirements of the PHS Act. Although some states lack direct state statutory authority to enforce, CMS has worked with many of these states to implement collaborative enforcement agreements. Through these agreements, a state performs the same regulatory functions with respect to the applicable individual and group insurance market requirements of Title XXVII of the PHS Act (market reform provisions) as it does to ensure compliance with state law, and seeks to achieve voluntary compliance from issuers if the state finds a potential violation. Similarly, consumers continue to contact the state with inquiries and to submit complaints relating to the market reform provisions. Under this collaborative approach, if the state finds a potential violation and is unable to obtain voluntary compliance from an issuer, it would refer the matter to CMS for possible enforcement action. If a state lacks authority or ability to enforce PHS Act requirements, then CMS would directly enforce the relevant market reform provisions in the state with respect to health insurance issuers in the group and individual markets. Finally, CMS directly enforces the relevant market reform provisions with

respect to non-Federal governmental plans in all states.

When CMS is responsible for enforcement with respect to issuers and non-Federal governmental plans, enforcement tools CMS uses in accordance with 45 CFR 150.301 through 150.347, include policy form review, complaint-driven investigations, and market conduct examinations. CMS also has authority to impose civil money penalties against health insurance issuers in a state in which CMS is directly enforcing the PHS Act, and against non-Federal governmental plan sponsors in all states that fail to comply with applicable PHS Act requirements.²⁸

The CAA adds additional PHS Act requirements that apply to group health plans, including non-Federal governmental plans, health insurance issuers, providers, including providers of air ambulance services (providers), and health care facilities (facilities). CMS would enforce these provisions to the extent they apply to non-Federal governmental plans in all states and to issuers in states where CMS directly enforces in the aforementioned manner. With respect to enforcement of the requirements applicable to providers and facilities, the CAA largely mirrors the current issuer enforcement structure: Namely, states are the primary enforcers, with CMS only enforcing if a state fails to substantially enforce, and these proposed rules reflect this structure. However, the provisions of section 106(a) of the No Surprises Act that apply to providers of air ambulance services are enforced directly by CMS. The CAA and these proposed rules would require CMS to follow the process set forth in section 1128A of the SSA to impose civil money penalties on providers or facilities for non-compliance with provisions of Part E of Title XXVII of the PHS Act and on providers of air ambulance services for non-compliance with the requirement to submit data under section 106(a) of the No Surprises Act. The applicable state authority involved in oversight and enforcement of providers and facilities would likely be different in most, if not all, states from the applicable state authority responsible for oversight and enforcement over health insurance issuers.

HHS proposes to make conforming amendments to existing regulations in subparts A, B, and D and to add a new subpart E to 45 CFR part 150 to provide for CMS direct enforcement when a state is not substantially enforcing PHS

Act requirements pertaining to providers and facilities and when a provider of air ambulance services fails to submit data required under section 106(e) of the No Surprises Act. HHS also proposes to amend existing regulations to add references to 45 CFR part 149, which implements these PHS Act requirements and to which the enforcement regulations in 45 CFR part 150 would also apply. Additionally, HHS proposes revising subpart C of 45 CFR part 150 to align these provisions with industry standards and clarify the existing CMS enforcement procedures, and equip CMS with additional tools to fulfill its enforcement responsibilities under the PHS Act.

HHS proposes revising the title of 45 CFR part 150 to reflect the extension of CMS's enforcement authority to providers and facilities in states that are not substantially enforcing the requirements in Part E of Title XXVII of the PHS Act and to providers of air ambulance services for purposes of the data submission requirements under section 106(e) of the No Surprises Act.

1. Basis and Scope (45 CFR 150.101)

HHS proposes to add to 45 CFR 150.101(a), which captures the basis of 45 CFR part 150, references to section 2799B-4 of the PHS Act, which subjects providers and facilities to the enforcement provisions of the PHS Act that HHS proposes to implement in 45 CFR part 150, and section 106(e) of the No Surprises Act, which subjects providers of air ambulance services to civil money penalties for failure to comply with data reporting requirements. HHS also proposes to make conforming edits to expand the scope of 45 CFR part 150 in 45 CFR 150.101(b), including to specifically outline the enforcement framework that HHS proposes to implement under subpart E of 45 CFR part 150. This includes proposed amendments to 45 CFR 150.101(b)(2) to add a reference to 45 CFR part 149 to expand the scope of the framework applicable to enforcement over health insurance issuers. In addition, HHS proposes to add a new paragraph (b)(3) to capture the scope of the framework applicable to enforcement over providers and facilities.

2. Definitions (45 CFR 150.103)

HHS proposes to amend 45 CFR 150.103 to revise the introductory text to add a reference to 45 CFR part 149 and to add definitions related to enforcement against providers and facilities. Specifically, HHS proposes to define the term "facility" for purposes of 45 CFR part 150 to mean a health care

facility, an emergency department of a hospital, and an independent freestanding emergency department, as those terms are defined in 45 CFR 149.30, and any other facility subject to the requirements in Part E of Title XXVII of the PHS Act. HHS also proposes to define the term "provider" for purposes of 45 CFR part 150 to mean a physician or other health care provider, as that term is defined in 45 CFR 149.30, as well as a provider of air ambulance services, as that term is defined in 45 CFR 149.30. These combined definitions would make 45 CFR part 150 easier to read and understand, as the enforcement procedures outlined in 45 CFR part 150 apply to all the aforementioned parties separately defined in 45 CFR 149.30. HHS also proposes to make conforming amendments to add references to 45 CFR part 149 to the definition of "individual health insurance policy or individual policy" and the definition of "PHS Act requirements." HHS seeks comment on these proposals.

3. State Enforcement (45 CFR 150.201)

Under 45 CFR 150.201, states have primary enforcement authority over health insurance issuers with respect to PHS Act requirements, unless the state notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing PHS Act requirements or the state fails to substantially enforce the PHS Act requirements that apply to issuers, in which case CMS would enforce those requirements. These proposed rules would make a conforming amendment at 45 CFR 150.201 to specify that states also have primary enforcement authority over providers and facilities that furnishes items or services to individuals in the state, unless the state notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing PHS Act requirements or the state fails to substantially enforce the PHS Act requirements that apply to providers and facilities, in which case CMS would enforce these requirements. Under this proposed rule, a state would be the primary enforcer of the PHS Act requirements against providers or facilities that furnish services via telehealth to individuals located in the state, even in circumstances where the provider or facility is located in a different state. While many states require licensure of out-of-state telehealth providers furnishing care to individuals within the state, HHS understands that this is not always true, and that many states have relaxed licensure requirements in response to

²⁸ See section 2723(b) of the PHS Act. Also see 45 CFR 150.301 through 150.347.

the COVID-19 public health emergency.²⁹ HHS seeks comment on whether the approach taken in this proposed rule presents challenges with respect to providers or facilities furnishing telehealth services.

HHS also proposes to make a technical correction to the title of subpart B to reflect that this subpart would apply to multiple PHS Act requirements rather than only one requirement. HHS proposes to revise the title of subpart B by changing “requirement” to “requirements” as the term should have been plural.

4. Circumstances Requiring CMS Enforcement (45 CFR 150.203)

HHS proposes to make technical corrections to the introductory language at 45 CFR 150.203 to reflect that this section would apply to multiple PHS Act requirements rather than only one requirement. HHS is not proposing further amendments because HHS would interpret and apply the current language outlining the circumstances requiring CMS enforcement, which generally refers to states, to situations involving providers and facilities in the same manner in which it applies to health insurance issuers in situations where the applicable state authority fails to substantially enforce applicable PHS Act requirements.

5. Sources of Information Triggering an Investigation of State Enforcement (45 CFR 150.205)

Section 150.205(d) provides that if information regarding the status of state enforcement of PHS Act requirements comes from state governors and commissioners of insurance, such information may trigger a CMS investigation of whether a state is failing to substantially enforce these requirements. Because governors, commissioners, and other applicable state insurance agency or entity leaders may not have oversight or enforcement authority over providers and facilities, information regarding state enforcement of PHS Act requirements with respect to providers and facilities may instead come from the state departments of health or other state agencies with that authority. Additionally, some states have officials distinct from the

commissioners of insurance who are responsible for regulating health maintenance organizations (HMOs). Therefore, HHS proposes to amend 45 CFR 150.205(d) to add a reference to officials responsible for regulating HMOs, directors of public health or any other state department, agency, or board with applicable oversight authority over entities subject to PHS Act requirements to the list of state officials who may be the source of information triggering an investigation. Proposed amendments to 45 CFR 150.205(e)(2) would correct a typographical error which incorrectly referenced in 45 CFR 148.120 instead of 45 CFR 148.210.

6. Notice to the State (45 CFR 150.211)

Under these proposed rules, in determining whether a state is failing to substantially enforce PHS Act requirements that apply to providers and facilities, CMS would use the processes and standards already established with respect to state enforcement of applicable PHS Act requirements with respect to health insurance issuers in 45 CFR 150.205 through 150.221. CMS is of the view that these processes can largely also apply to state enforcement of the new PHS Act requirements applicable to providers and facilities without change. However, the current regulatory language at 45 CFR 150.211 specifies that if there is a reasonable question regarding state enforcement, CMS will send a notice to the governor or chief executive officer of the state, the insurance commissioner or chief insurance regulatory official, or the official responsible for regulating HMOs. Those individuals may not be the appropriate recipients if there is a reasonable question regarding state enforcement of PHS Act requirements that apply to providers or facilities. Therefore, HHS proposes to amend 45 CFR 150.211 to add paragraph (d) specifying that a notice of possible failure to substantially enforce PHS Act requirements in such circumstances would be sent to the relevant state official responsible for regulating providers and facilities and to make conforming changes to paragraph (b) to reflect that notices would be sent to the insurance commissioner or chief insurance regulatory official when there is a reasonable question regarding state enforcement of PHS Act requirements that apply to health insurance issuers. Paragraph (c) would be retained, which provides that such notices would be sent to the state official responsible for regulating HMOs, if different from the official listed in paragraph (b), when the alleged failure involves HMOs.

7. Transition to State Enforcement (45 CFR 150.221)

HHS proposes to make conforming amendments to 45 CFR 150.221(a)(2) to provide that the discussions between CMS and state officials regarding transition to state enforcement would include instructions to providers and facilities, rather than instructions only to issuers. HHS also proposes to amend 45 CFR 150.221(b) to similarly add references to providers and facilities to make clear that CMS may also negotiate a process to ensure that, to the extent practicable, and as permitted by law, its records documenting compliance and other relevant areas of CMS's enforcement operations are made available for incorporation into the records of the applicable state authority responsible for oversight and enforcement of providers and facilities. These proposed changes would capture a reference to the new PHS Act requirements enacted in the CAA applicable to providers and facilities to ensure the regulation includes situations where a transition back to state enforcement of applicable Federal requirements over such entities is appropriate. HHS also proposes to replace the language about making CMS enforcement records available to states by removing the language about “incorporation into the records” of the State regulatory authority that would assume enforcement to more generally refer to making such records available to the State regulatory authority.

8. Basis for Initiating an Investigation (45 CFR 150.303)

Currently, 45 CFR 150.303 provides that if CMS receives information that an issuer or non-Federal governmental plan may be failing to meet a PHS Act requirement, then an investigation may be warranted. HHS proposes to revise 45 CFR 150.303(a) to specify that CMS may undertake either an investigation or a market conduct examination, rather than only an investigation, within its discretion based on this information. This proposed revision would align 45 CFR 150.303(a) with the regulatory text in 45 CFR 150.313(b), which provides that CMS may initiate a market conduct examination when, based on the information described in 45 CFR 150.303, it finds evidence that a specific entity may be in violation of the PHS Act.

When determining whether to undertake an investigation or examination, CMS would consider a number of different factors, including the facts and circumstances surrounding the potential violation, the potential

²⁹ See, for example, Center for Connected Health Policy. *Cross-State Licensing*. Available at: <https://www.cchpca.org/topic/cross-state-licensing-professional-requirements/> (last accessed August 8, 2021); and Federation of State Medical Boards. *U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19*. (July 28, 2021.) Available at: <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>.

number of impacted consumers, an issuer or non-Federal governmental plan's past history of substantiated complaints, the effect of the alleged violation on a consumer, the deterrent effect that knowledge of the investigation or examination may have on others who may consider committing similar violations, and other considerations that CMS deems appropriate.

HHS further proposes to revise 45 CFR 150.303(a) to add a new sentence to clarify that CMS may review any information it deems useful to determine if a violation of the PHS Act has occurred when undertaking an investigation or examination. HHS proposes this change to more clearly describe current CMS procedures, which may include a review of applicable data and documentation, such as paid and denied claims, summary plan documents, summary of benefits and coverage, and notifications to enrollees, to assess whether the entity may be in violation of the PHS Act. Additionally, HHS proposes a conforming amendment to paragraph (a)(2) to capture a reference to reports from providers and facilities—along with reports from state insurance departments, the NAIC and other Federal and state agencies—as potential sources or types of information that could lead to an investigation or examination to ensure compliance with the applicable PHS Act requirements.

HHS proposes to remove and replace 45 CFR 150.303(c), which currently states that a complaint may be directed to any CMS regional office. HHS proposes this change because the CMS regional offices no longer process complaints. Instead, CMS offers several methods for entities or individuals to submit complaints. These methods vary based on the type of coverage or plan in which an individual is enrolled and the substance of the complaint, and are described on CMS's public web pages. For PHS Act complaints regarding non-Federal governmental plans, consumers can email PHIG@cms.hhs.gov. For complaints with respect to issuers, consumers in states that are directly enforcing the applicable PHS Act provision are referred to the state department of insurance; for states in which CMS is directly enforcing PHS Act requirements, consumers can email MarketConduct@cms.hhs.gov. The list of current states in which CMS is directly enforcing one or more PHS Act provisions is available on the CMS website at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/compliance>.

HHS proposes to remove the complaint provision that is currently in 45 CFR 150.303(c), and replace it with a new provision specifying that CMS may conduct random or targeted investigations and market conduct examinations of issuers and non-Federal governmental plans to ensure compliance with the PHS Act. HHS is proposing this regulation to codify another enforcement tool for CMS for situations where it is responsible for enforcement of the Federal market reform provisions. The proposal is also intended to codify in regulation the new statutory obligations established under the CAA for HHS to conduct certain specified audits and reviews. More specifically, section 2799A–1(a)(2)(A)(ii) of the PHS Act directs HHS to conduct audits of a sample of claims data with respect to a year (beginning with 2022) from not more than 25 group health plans and health insurance issuers offering group or individual health insurance coverage to verify compliance with the qualifying payment amount requirements described in section 2799A–1 of the PHS Act, as enacted by the No Surprises Act. HHS expects states with primary enforcement authority with respect to section 2799A–1 of the PHS Act will carry out enforcement activities to verify compliance with the qualifying payment amount requirements in section 2799A–1 of the PHS Act and 45 CFR 149.140 to the extent that the qualifying payment amount is used to determine the “recognized amount” for purposes of calculating cost sharing under section 2799A–1. As noted in 45 CFR 149.140(f), HHS intends to carry out these statutory provisions in states in which CMS is directly enforcing using the market conduct examination procedures described in 45 CFR 150.313, as proposed to be amended, when conducting random and targeted audits for compliance with the requirements for applying a qualifying payment amount.³⁰ Additionally, section 203 of Title II of Division BB of the CAA amended section 2726(a) of the PHS Act to expressly require group health plans and health insurance issuers offering group or individual health insurance coverage³¹ that provide both medical/surgical (M/S)

³⁰ 86 FR 36899 and 36979 (July 13, 2021).

³¹ Pursuant to section 2723(b)(1) of the PHS Act, CMS enforces section 2726 of the PHS Act and other applicable provisions of Title XXVII of the PHS Act with respect to non-Federal governmental group health plans in all states and with respect to health insurance issuers selling products in the individual and fully insured group markets in states that elect not to enforce or fail to substantially enforce section 2726 of the PHS Act and other applicable provisions of Title XXVII of the PHS Act.

benefits and mental health or substance use disorder (MH/SUD) benefits and that impose nonquantitative treatment limitations (NQTLs) on MH/SUD benefits to perform, document, and make available upon request to HHS (or the applicable state authority) comparative analyses of the design and application of their NQTLs. PHS Act section 2726(a)(8)(B), as added by section 203 of Title II of Division BB of the CAA further directs HHS to request, review, and report to Congress its findings regarding NQTL comparative analyses from group health plans and health insurance issuers each year. In order to satisfy the newly codified statutory obligations for HHS to conduct these specified audits and reviews under the CAA, CMS currently intends to focus random or targeted investigations under the new proposed 45 CFR 150.303(c) on ensuring compliance with (i) qualifying payment amount requirements described in section 2799A–1 of the PHS Act, which was added by the No Surprises Act, and (ii) the NQTL comparative analysis requirements described in section 2726(a)(8) of the PHS Act. CMS is committed to robust enforcement of these new requirements and ensuring compliance with other applicable PHS Act provisions. HHS is of the view that this is a necessary and appropriate exercise of its enforcement and rulemaking authorities under sections 2723 and 2792 of the PHS Act, respectively. Further, HHS is of the view that having authority to conduct random or targeted investigations or examinations for all PHS Act provisions, including but not limited to qualifying payment amount requirements described in section 2799A–1 of the PHS Act, which was added by the No Surprises Act and codified in regulations at 45 CFR 149.140, and the NQTL comparative analysis requirements described in section 2726(a)(8) of the PHS Act, would create a more efficient and effective enforcement program in that CMS would be able to proactively ensure consumers are receiving the benefits to which they are entitled rather than having to wait to receive a complaint or other information indicating a potential PHS Act violation in situations where CMS is responsible for enforcement. For example, an investigation or examination by CMS of one responsible entity may identify a potential systematic error or issue that the agency suspects may impact similarly situated entities subject to CMS's enforcement authority. These proposed rules would provide CMS

with another enforcement tool to investigate whether these other entities have experienced the same error or issue without having to wait to receive a complaint or other information indicating a PHS Act violation to take action.

HHS also proposes a conforming amendment to the title for this section to also capture a reference to examinations and to remove the reference to a potential violation. This would align with the proposed amendments to 45 CFR 150.303, as outlined in this section of the preamble, to allow CMS to randomly select non-Federal governmental plans and issuers for investigation and market conduct examination to ensure compliance with applicable PHS Act requirements when CMS is responsible for enforcement, as well as the other amendments to 45 CFR 150.303 to specify that CMS may also undertake an examination based on information the agency receives that an issuer or non-Federal governmental plan may be failing to meet a PHS Act requirement.

HHS seeks comment on these proposed changes.

9. Notice to Responsible Entities (45 CFR 150.307)

HHS proposes to revise several provisions in 45 CFR 150.307 regarding the notice that is sent to responsible entities when there is a potential violation, to reflect and clarify the current CMS enforcement procedures. The proposed revisions are further intended to provide responsible entities additional information and clarity regarding CMS's authority and process for conducting investigations.³² Specifically, HHS proposes to replace the word "investigation" with "information" in the introductory text to align this section with the regulatory text in 45 CFR 150.303, which generally addresses information that may warrant an investigation or an examination. HHS is also proposing to revise the introductory text to clarify that the notice would also be sent to initiate investigations of randomly selected non-Federal governmental plans and issuers under new proposed 45 CFR 150.303(c). The proposed revision to the introductory text also provides that CMS would also send this notice to the responsible entity or entities in situations where information received under 45 CFR 150.303(a) indicates a potential violation. HHS is also

proposing to remove the provision in 45 CFR 150.307(a), which currently states that the notice describes the substance of the complaint or other information received, and to replace it with a new provision specifying that the notice describes the information received under 45 CFR 150.303 that gives rise to the investigation or notifies the responsible entity that it was selected by CMS for a random investigation under 45 CFR 150.303(c). HHS is proposing this change to clarify that CMS does not provide personally identifiable information (PII) or PHI via a complaint without the complainant's express consent. HHS also would not disclose confidential or other sensitive information protected from disclosure that may be included in the complaint. However, the notice would include other information sufficient to explain the potential violation(s) and provide the responsible entity an adequate opportunity to respond to the allegation(s), or to notify the responsible entity of its selection for, and the PHS Act provision(s) that are the focus of, a random investigation under new proposed 45 CFR 150.303(c).

Consistent with current text at 45 CFR 150.307(b), CMS generally contacts the responsible entity once it reviews the information received under 45 CFR 150.303 and provides the responsible entity 30 days to respond with additional information, including documentation of compliance as described in 45 CFR 150.311. CMS also directs the responsible entity to submit any data or documentation that CMS identifies as relevant and may use to assess whether the responsible entity is violating applicable PHS Act provisions. However, there are circumstances in which CMS has determined it is not appropriate to provide the responsible entity 30 days to respond. Such circumstances include complaints involving urgent medical issues, allegations of fraud or abuse, and when CMS must complete the investigation within a specified time frame under the statute. Accordingly, CMS proposes to revise 45 CFR 150.307(b) to clarify that the notice provided under this section would direct the responsible entity to provide any documentation that CMS identifies as relevant to the investigation, in addition to other documentation, such as documentation of compliance as described in 45 CFR 150.311, that in the responsible entity's view would aid CMS in evaluating the allegations and the entity's compliance with the PHS Act requirements identified in the notice. HHS further proposes to revise 45 CFR 150.307(b)

such that CMS would provide the date by which the responsible entity must respond to the notice; the goal is to ensure the efficient administration of investigations. CMS anticipates generally providing 14 days for response. In circumstances that warrant a more rapid response, CMS anticipates providing at least 24 hours for response. In circumstances that warrant additional time, such when CMS requests large amounts of data, CMS anticipates providing more than 14 days for response. HHS is not proposing any amendments to 45 CFR 150.307(c) and therefore would retain the requirement that the notice also inform the responsible entity that a civil money penalty may be assessed. Lastly, under the new proposed 45 CFR 150.307(d), the notice would also inform responsible entities that CMS may require the responsible entity to take certain corrective actions as necessary to bring it into compliance with the applicable PHS Act requirements. HHS believes it is necessary and appropriate to highlight, as part of this notice, that corrective actions may be required because, similar to the potential for a civil money penalty to be assessed, this is another potential outcome of an investigation.

HHS seeks comment on these proposed changes.

10. Request for Extension (45 CFR 150.309)

HHS is proposing conforming amendments to revise 45 CFR 150.309 by removing the references to 30 days and clarifying that a responsible entity may request an extension when it cannot prepare a response or provide the requested information to CMS by the deadline provided in the notice under 45 CFR 150.307, and that failure to respond by the initial deadline provided in the notice or an extended deadline granted by CMS may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a violation of PHS Act requirements. To align with proposed amendments to 45 CFR 150.313, HHS proposes to codify examples of what CMS would consider good cause, which include but are not limited to situations when a responsible entity indicates it has limited staffing resources to prepare a response, or when a responsible entity requests clarification from CMS regarding its request for information.

11. Responses to Allegations of Noncompliance (45 CFR 150.311)

HHS proposes a conforming revision at 45 CFR 150.311(e) to add a reference

³² HHS is not proposing to incorporate a reference to market conduct examinations in 45 CFR 150.307 due to the separate regulation, 45 CFR 150.313, that addresses and details CMS's authority and processes for conducting such examinations.

to the proposed notice to initiate a market conduct examination under new proposed 45 CFR 150.313(e), which is described in section III.C.12 of the preamble.

12. Market Conduct Examinations (45 CFR 150.313)

The proposed revisions to 45 CFR 150.313 would bring this rule in line with standard industry practices adopted by the NAIC, which CMS generally follows, and would also codify additional CMS procedures for market conduct examinations. HHS also proposes several amendments to reorganize the order and presentation of information in this regulation to improve clarity.

First, HHS proposes to remove the last sentence in 45 CFR 150.313(b) as the proposed adoption of 45 CFR 150.313(f), which would outline the requirements for responsible entities to provide the requested documentation to CMS, make this sentence unnecessary. HHS further proposes to revise 45 CFR 150.313(b) to clarify that CMS may initiate a market conduct examination of a randomly selected non-Federal governmental plan or issuer subject to CMS's enforcement authority. This change would align with the proposed revision at 45 CFR 150.303(c).

Second, HHS proposes to revise 45 CFR 150.313(c) to clarify that CMS would appoint examiners when CMS initiates a random market conduct examination. Conforming amendments are also proposed to the opening clause of 45 CFR 150.313(c) to replace the current reference to "investigation" with "further review" to more clearly distinguish the authority to initiate a market conduct examination from the authority to conduct an investigation.

HHS additionally proposes to redesignate 45 CFR 150.313(e)(1) and (2) as 45 CFR 150.313(h)(1) and (2) and also proposes to replace the title of the newly designated section to clarify that it pertains to a draft market conduct examination report. HHS also proposes to revise 45 CFR 150.313(e)(1), proposed to be redesignated at 45 CFR 150.313(h)(1), to remove the description of CMS review of the draft report and replace it with a general statement indicating that upon completion of the examination, CMS would compose and provide a draft report to the responsible entity. HHS further proposes to include in redesignated 45 CFR 150.313(h)(1) a description of the contents of the draft report. Under current CMS market conduct examination practices and as reflected in the second sentence in proposed 45 CFR 150.313(h)(1), the draft report would include the scope of

the examination, any findings of a PHS Act violation, and any proposed actions the entity would need to take to correct such violation. The entity then has an opportunity to respond to the draft report and either concur with the draft report findings or disagree. As reflected in proposed 45 CFR 150.313(h)(2)(i), if the responsible entity agrees with one or more of the findings in the draft report, the entity can inform CMS of any corrective action planned or already undertaken. If the entity disagrees with one or more of the findings, then the entity may provide evidence to CMS to support its disagreement. This is included in proposed 45 CFR 150.313(h)(2)(ii).

HHS further proposes to redesignate 45 CFR 150.313(e)(3), which currently addresses CMS's reply to a response to the market conduct examination report from the responsible entity, as a new 45 CFR 150.313(i) and revise it so it instead pertains to the final market conduct examination report. In the new proposed introductory sentence, HHS proposes that upon receipt of a response from the responsible entity under new paragraph (h)(2), CMS would provide a final examination report containing the agency's findings relevant to each examination issue, including the agency's reply to the responsible entity's responses to the findings in the draft report for each examination issue. HHS also proposes to replace the current references to issuer or non-Federal governmental plan with references to responsible entity in the redesignated 45 CFR 150.313(i)(1) through (4), currently codified at 45 CFR 150.313(e)(3)(i) through (iv), for consistency in terminology. HHS also proposes to clarify CMS's review and response to the responsible entity's corrective actions, if applicable, in 45 CFR 150.313(i)(3) and (4). Under current CMS market conduct examination practices and the proposed 45 CFR 150.313(i), this report finalizes the draft report and includes the entity's concurrence or disagreement with each cited PHS Act violation, and CMS's responses thereto. As detailed in 45 CFR 150.313(i)(1) through (5), CMS's reply would consist of one or more of the following: (1) Concurrence with the responsible entity's position; (2) disagreement with the responsible entity's position; (3) a determination that the corrective actions implemented by the responsible entity sufficiently addressed the identified PHS Act violation; (4) a determination that the corrective actions implemented by the responsible entity have not sufficiently addressed the identified PHS Act

violation, and information on any further corrective actions deemed necessary by CMS; or (5) a notice to the responsible entity that has disagreed with a CMS finding and that has not undertaken corrective actions that there exists a violation of applicable PHS Act requirements and any actions the responsible entity must take to correct such violation. These changes are designed to align HHS regulations with industry standards for market conduct examinations. These industry standards, promulgated by NAIC, are used throughout the country by states and issuers and are generally followed by CMS. The adoption in regulation of the standard industry practices and procedures would bring uniformity to the framework CMS and the various states use to undertake market conduct examinations.

HHS proposes to add new text at 45 CFR 150.313(e) to provide that CMS would initiate a market conduct examination by providing written notice to the responsible entity and to describe the substance of the examination notice call letter CMS would send to an entity to initiate a market conduct examination. HHS proposes that this would be a written notice from CMS to the responsible entity and that it would include the following information: (1) A description of the information received under 45 CFR 150.303(a) that served as the basis for CMS's determination that a market conduct examination was warranted or notification that the entity was selected by CMS for a market conduct examination under 45 CFR 150.303(c); (2) a description of the scope of the examination; (3) the identification of the examiners; (4) a statement that a civil money penalty may be assessed; and (5) a statement that CMS may require a plan of corrective action. HHS is of the view that this set of core information, which is intended to mirror the information provided in the notice to responsible entities under 45 CFR 150.307 when CMS initiates an investigation, is the appropriate vehicle to commence a market conduct examination and is standard industry practice.

HHS also proposes to add 45 CFR 150.313(f) to generally describe the documentation collection and the initial directive for the responsible entity to submit the information that CMS identifies as relevant for the examination, the time frame for the entity's response, and to specify the penalties for failing to respond timely, which may include civil money penalties. This initial directive would provide the deadline by which responsible entities must forward the

requested documentation or request an extension. Any extension request would be required to be submitted in writing, detail the reasons for the extension request and show good cause. CMS would consider the following circumstances a non-exhaustive list of examples of good cause: (i) Limited staffing resources to prepare a response, or (ii) when a responsible entity requests clarification from CMS regarding its request for information. If CMS grants the extension, the responsible entity would be required to respond to the documentation request within the time frame specified in CMS's letter granting the extension request. The new proposed language in 45 CFR 150.313(f) also specifies that if the responsible entity fails to respond within the initial deadline provided or within the extended time frame (if granted by CMS), then CMS may impose a civil money penalty based on the information provided in the complaint or other information alleging or indicating a violation of PHS Act requirements. New proposed 45 CFR 150.313(f) would also capture the opportunity for the responsible entity to provide additional information, including documentation of compliance as described in 45 CFR 150.311, that the responsible entity believes would aid CMS in conducting the examination.

HHS also proposes to add 45 CFR 150.313(g) to describe the fieldwork CMS undertakes during a market conduct examination. Under current CMS practices and as reflected in new proposed 45 CFR 150.313(g), during the course of the examination, CMS may request additional information or documentation to support the review of the entity's data or other documents to assess the responsible entity's compliance with applicable PHS Act requirements. The request for additional information or documentation would specify the time frame allotted for the responsible entity to respond and forward the requested materials. Similar to the proposed initial documentation requests, HHS proposes to capture a similar framework that permits responsible entities to make a written request for an extension from CMS detailing the reason(s) for the request and showing good cause. Examples of what CMS would consider good cause include, but are not limited to, when a responsible entity indicates it has limited staffing resources to prepare a response, or when a responsible entity requests clarification from CMS regarding its request for information. If CMS grants the extension, the responsible entity would be required to

respond to the documentation request within the time frame specified in CMS's letter granting the extension request. As detailed in the new proposed 45 CFR 150.313(g), the failure to respond and provide such additional requested documentation within the initial time frame, or within the extended time frame (if granted by CMS), may result in CMS's imposition of a civil money penalty based upon the complaint or other information when there is sufficient evidence indicating a violation of applicable PHS Act requirements. This new proposed rule also states that, during the examination, CMS may identify and notify the responsible entity of any potential PHS Act violations and, in such circumstances, would provide the entity an opportunity to respond and submit evidence of its compliance or other documentation the responsible entity believes would aid CMS in conducting the examination.

HHS seeks comment on these proposed changes.

13. Determining the Amount of the Penalty—Mitigating Circumstances (45 CFR 150.319)

HHS proposes to make a conforming edit to 45 CFR 150.319 to add reference to the notice to initiate a market conduct examination under the new proposed 45 CFR 150.313(e).

14. Determining the Amount of Penalty—Aggravating Circumstances (45 CFR 150.321)

HHS proposes to amend 45 CFR 150.321 to add a new paragraph (d), which would specify that an entity's failure to cooperate with an investigation or market conduct examination would be considered an aggravating circumstance for purposes of determining the aggregate amount of a penalty. HHS is proposing this additional aggravating circumstance based on CMS's experience conducting examinations and investigations. More specifically, HHS has experienced situations where responsible entities fail to respond to requests for information in a timely fashion or otherwise generally fail to cooperate in a CMS enforcement action. For example, in one market conduct examination, an issuer failed to respond to CMS's requests for information for 6 months thereby causing significant delay to the examination. HHS is of the view that it is appropriate and necessary to add this additional aggravating circumstance to provide CMS a vehicle to increase the amount of a civil money penalty (up to but not in excess of the statutory maximum) in situations when the

responsible entity fails to cooperate with a CMS investigation or market conduct examination and there is sufficient evidence indicating a violation of an applicable PHS Act requirement to discourage these behaviors.

HHS seeks comment on this proposed change.

15. Settlement Authority (45 CFR 150.325)

HHS proposes to make a conforming edit to 45 CFR 150.325 to add reference to the notice to initiate a market conduct examination under the new proposed 45 CFR 150.313(e).

16. Definitions (45 CFR 150.401)

HHS proposes to make a conforming amendment to the definition of respondent to add a reference to a notice of proposed determination of a civil money penalty issued under the proposed new 45 CFR 150.515. This proposed amendment would provide for the same process for administrative hearings regarding civil money penalties assessed against providers and facilities as the process established for non-Federal governmental plans and issuers in states where CMS directly enforces PHS Act requirements.

17. Filing of Request for Hearing (45 CFR 150.405)

HHS proposes to make a conforming edit to 45 CFR 150.405(a) to add reference to a notice of proposed determination of a civil money penalty issued under the new proposed 45 CFR 150.515. This would provide providers and facilities 30 days from the date of such notice to request a hearing with an administrative law judge to appeal the proposed determination. This would align with the existing time frame provided to non-Federal governmental plans and issuers for such appeals in states where CMS directly enforces PHS Act requirements.

18. Issues To Be Heard and Decided by ALJ (45 CFR 150.417)

HHS proposes to make a conforming amendment to add a reference to proposed 45 CFR 150.513 for factors an Administrative Law Judge (ALJ) can apply to determine the reasonableness of a civil money penalty. This proposed amendment would provide for the same process for administrative hearings regarding civil money penalties assessed against providers and facilities as the process established for non-Federal governmental plans, and issuers in states where CMS directly enforces PHS Act requirements.

19. Evidence (45 CFR 150.445)

HHS proposes to make conforming amendments to 45 CFR 150.445(g), which pertains to admissibility of evidence of acts other than those at issue in the instant case, to add references to the proposed 45 CFR 150.513 (which describes factors and mitigating and aggravating circumstances considered in determination of the amount of civil money penalty assessed against a provider or facility), and proposed 45 CFR 150.505 and 150.515 (which describe notices sent by CMS to responsible entities regarding potential violations and civil money penalties against a provider or facility). HHS proposes to make a similar conforming amendment to 45 CFR 150.445(j), which pertains to admissibility of evidence of willingness and ability to enter into and complete a corrective action plan, to add a reference to proposed 45 CFR 150.505. These proposed amendments would provide for the same process for administrative hearings regarding civil money penalties assessed against providers and facilities as the process established for non-Federal governmental plans, and issuers in states where CMS directly enforces PHS Act requirements. In addition, HHS proposes to amend 45 CFR 150.445(h) to provide for cross-examination of witnesses, to conform to (i) the right to cross-examination already implicit in 45 CFR 150.419, and (ii) section 1128A(c)(2) of the SSA, as required in section 2799B–4 of the PHS Act. The right to cross-examine witnesses is fundamental and is being explicitly included here to ensure that the process for hearings is fair for all parties.

20. Sanctions (45 CFR 150.455)

HHS proposes to amend 45 CFR 150.455 to add the payment of an aggrieved party's attorneys' fees and other costs as an additional sanction for violations of 45 CFR part 149, to conform to section 1128A(c)(4) of the SSA. Section 2799B–4 of the PHS Act subjects civil money penalties assessed under that section to the requirements in section 1128A(c) of the SSA (with the exception of the first sentence of section 1128A(c)(1)). Section 1128A(c)(4) of the SSA provides that an ALJ may sanction parties and attorneys for "failing to comply with an order or procedure, failing to defend an action, or other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing." Subsection (g) thereof specifically provides for ordering the party or attorney to pay attorneys' fees

and other costs caused by the failure or misconduct.

D. 45 CFR Part 150, Subpart E—CMS Enforcement With Respect to Providers and Facilities

HHS proposes to add a new subpart E to 45 CFR part 150, to implement the requirements of section 2799B–4 of the PHS Act. This new subpart would specify the CMS enforcement processes with respect to the requirements of Part E of Title XXVII of the PHS Act (and its implementing regulations at 45 CFR part 149) that would be applicable to providers and facilities subject to CMS's enforcement authority. With respect to potential violations of these requirements, HHS proposes to follow a similar investigatory process to that which currently exists in subpart C of 45 CFR part 150, which applies to investigations of possible violations by plans and issuers. HHS is proposing to use that similar process to maximize efficiency. HHS believes that the general steps of reviewing complaints or other indications of a potential PHS Act violation, notifying responsible parties of the investigation and directing them to provide information and documentation for CMS to review and assess compliance, and directing the responsible party to take corrective actions to remedy any violations identified are prudent and appropriate to apply to investigations of providers and facilities. HHS believes that this proposed approach would allow CMS to effectively enforce the new requirements and ensure that providers and facilities are sufficiently informed of the steps in and how to comply with the investigation process.

In contrast, HHS is proposing a different civil money penalty process to comply with the statutory requirements of the No Surprises Act. Section 2799B–4 of the PHS Act delineates the process for imposition of civil money penalties if a provider or facility is found to be in violation of Part E of Title XXVII of the PHS Act. Section 106(e) of the No Surprises Act sets forth the process for imposition of civil money penalties if a provider of air ambulance services fails to provide data required in section 106(a) of the No Surprises Act. In both cases, the process must follow section 1128A of the SSA.³³ Therefore,

³³ The applicability of section 1128A of the SSA varies depending on the applicable enforcement provision. For violations stemming from Section 2799B–4 of the PHS Act, provisions of subsections (c) (with the exception of the first sentence of paragraph (1) of such subsection), (d), (e), (g), (h), (k), and (l) apply. For violations stemming from Section 106 of the No Surprises Act, all provisions other than subsections (a) and (b) and the first sentence of subsection (c)(1) apply.

although many of the investigative processes applicable to providers and facilities are the same as those applicable to plans and issuers, HHS proposes to codify the provider and facility enforcement procedures in new subpart E to 45 CFR part 150.

21. General Rule Regarding the Imposition of Civil Money Penalties (45 CFR 150.501)

Section 2799B–4 of the PHS Act authorizes HHS to apply a civil money penalty with respect to a provider or facility that is found to be in violation of Part E of Title XXVII of the PHS Act. Section 106(e) of the No Surprises Act authorizes HHS to apply a civil money penalty with respect to a provider of air ambulance services that fails to submit all information required under section 106(a) of the No Surprises Act by the required date. HHS proposes to codify those provisions in 45 CFR 150.501.

22. Basis for Initiating an Investigation; Injunctive Relief (45 CFR 150.503)

HHS proposes that CMS may conduct an investigation based on any information that indicates a provider or facility is failing to comply with PHS Act requirements. Proposed 45 CFR 150.503(a) would list the same sources of information as those that CMS may consider when investigating potential violations by plans or issuers, including complaints (such as complaints received under the process established in 45 CFR 149.150 with respect to plans and issuers or 45 CFR 149.450 with respect to providers and facilities), reports from state insurance departments, the NAIC, other Federal and state agencies, and any other information that indicates potential noncompliance with PHS Act requirements. HHS proposes to add state health and medical boards as additional sources in 45 CFR 150.503(a), as they may be relevant sources to indicate potential noncompliance by providers and facilities.

HHS proposes language in 45 CFR 150.503(b) that would clarify who may file a complaint. This would include any entity or individual, or any entity or personal representative acting on that individual's behalf, who believes that a right to which the aggrieved person is entitled under PHS Act requirements is being, or has been, denied or abridged as a result of any action or failure to act on the part of a provider or facility. This would ensure consistency with 45 CFR 150.303(b) which provides that such individuals or entities may submit a complaint with respect to non-Federal governmental plans and issuers.

HHS proposes in 45 CFR 150.503(c) to establish CMS's authority to conduct

random or targeted investigations of providers and facilities. This would allow CMS to proactively identify and address issues of non-compliance, and it would generally align CMS's enforcement procedures with respect to providers and facilities with those applicable to non-Federal governmental plans and issuers under newly proposed 45 CFR 150.303(c), but would exclude any reference to market conduct examinations, as these are typically used in connection with group health plans and health insurance issuers, and not with providers.

HHS proposes to codify in 45 CFR 150.503(d) the statutory language, located at section 1128A(k) of the SSA and included via section 2799B-4 of the PHS Act, that allows HHS to bring an action to prevent a provider or facility from engaging in activity that would make the provider or facility subject to a civil money penalty. HHS also proposes that CMS may bring an action to prevent a provider or facility from concealing, removing, encumbering, or disposing of assets that may be required in order to pay any civil money penalty that might be imposed or to seek other appropriate relief.

23. Notice to Responsible Entities (45 CFR 150.505)

HHS proposes to specify in 45 CFR 150.505 that if CMS receives information that indicates a possible violation, or selects a provider or facility for investigation, or fails to receive data required in 45 CFR 149.460, CMS would provide a written notice to the provider or facility. The notice would describe the information that prompted the investigation or notify the provider or facility that it was selected for investigation. The notice would also state that a civil money penalty may be assessed, and that CMS may require a plan of corrective action. The notice would provide the date by which the provider or facility must respond with additional information, including documentation of compliance. In the case of a provider of air ambulance services, this could include a date by which the provider of air ambulance services would be required to submit any missing information from the report required under 45 CFR 149.460. HHS anticipates that CMS would generally provide 14 days for providers and facilities to respond to the notice with the requested documentation. This would provide sufficient time for a recipient to investigate the substance of an allegation and respond to CMS. HHS anticipates that the documentation or information necessary to respond to most complaints should be readily

available to a provider (for example, in the form of computerized patient billing records, etc.). A 14-day window for response should provide sufficient time to gather this documentation and formulate a response. In circumstances that warrant a more rapid response, such as complaints involving urgent medical issues or allegations of fraud and abuse, CMS may shorten the time frame for the provider or facility to provide the requested documentation but does not anticipate requesting responses within less than 24 hours.

24. Request for Extension (45 CFR 150.507)

HHS proposes to provide in 45 CFR 150.507 that if a provider or facility received a notice of possible violation from CMS, and the provider or facility could not prepare a response by the deadline provided in the notice under 45 CFR 150.505, such provider or facility may make a written request for an extension. The request must detail the reason for the extension request and must show good cause. Examples of what CMS would consider good cause include, but are not limited to, when a responsible entity indicates it has limited staffing resources to prepare a response, or when a responsible entity requests clarification from CMS regarding its request for information. If CMS grants the extension, the provider or facility would be required to respond within the specified time frame. Failure to respond within the time allotted would result in CMS initiating an action to impose a civil money penalty.

25. Responses to Notice of Potential Violations (45 CFR 150.509)

HHS proposes to provide in 45 CFR 150.509 that CMS would consider all relevant documentation provided when determining whether to impose a civil money penalty, including information from the complainant and information from the provider or facility. In responding to an allegation of noncompliance, a provider or facility may submit medical bills; notice and consent forms signed by the participant, beneficiary, or enrollee (or an authorized representative); proof of public disclosure of patient protections against balance billing; or any other evidence of compliance.

In 45 CFR 150.509(d), HHS proposes that a provider or facility may also submit to CMS any evidence documenting the development and implementation of internal policies and procedures to ensure compliance with the PHS Act and section 106(a) of the No Surprises Act, as applicable. One example would be a voluntary

compliance program. A voluntary compliance program should, at a minimum: Effectively articulate and demonstrate the fundamental mission of compliance and the provider or facility's commitment to the compliance process; include the name of the individual in the organization who is responsible for compliance; include an effective monitoring system to identify practices that do not comply with PHS Act requirements or section 106(a) of the No Surprises Act, as applicable, and to provide reasonable assurance that violations are detected in a timely manner; and address procedures to improve internal policies when noncompliant practices are identified.

In 45 CFR 150.509(e), HHS proposes that a provider or facility may respond to an allegation of noncompliance by submitting evidence documenting the provider or facility's record of previous compliance with PHS Act requirements or section 106(a) of the No Surprises Act, as applicable. Examples of previous compliance would include copies of signed notice and consent forms or prominently displayed disclosures of patient protections against balance billing.

Section 106(e)(2) of the No Surprises Act provides that HHS may waive a penalty when a provider of air ambulance services submits only some of the data required in section 106(a) of the No Surprises Act if the provider of air ambulance services makes a good faith effort to submit the missing data. In 45 CFR 150.509(f), HHS proposes that such a provider can exhibit a good faith effort by submitting and implementing a corrective action plan that: (i) Identifies the cause underlying the submission of incomplete data and effectively articulates and demonstrates the measures that would be taken to submit complete data; (ii) provides the timeline for submitting complete data; (iii) provides the name of the individual in the organization responsible for overseeing corrective actions and submitting complete data; and (iv) addresses procedures to improve internal policies to ensure that incomplete data reports are identified and completed prior to submission for future reporting periods. HHS is of the view that these elements would demonstrate that a provider of air ambulance services is committed to identifying and correcting any errors that prevented it from submitting the complete set of data required. HHS seeks comment on this proposal.

26. Liability for Penalties (45 CFR 150.511)

In 45 CFR 150.511, HHS proposes to codify the provision in section 1128A(c)(1) of the SSA that provides that HHS will not commence any action to impose a civil money penalty unless such action is commenced within 6 years from the date when the violation occurred.

HHS also proposes that a principal is liable for penalties for the actions of the principal's agent acting within the scope of his or her agency, without limiting the underlying liability of the agent.

27. Amount of Penalty (45 CFR 150.513)

At 45 CFR 150.513(a)(1), HHS proposes to codify the statutory language that permits HHS to impose a civil money penalty in an amount not to exceed the sum of \$10,000 per violation if a provider or facility is found to be in violation of a PHS Act requirement. At 45 CFR 150.513(a)(2), HHS proposes to codify the statutory language found in section 106(e) of the No Surprises Act that permits HHS to impose a civil money penalty in an amount not to exceed the sum of \$10,000 if a provider of air ambulance services fails to submit required data. Such civil money penalties would be in addition to any other penalties prescribed or allowed by law.

HHS proposes that CMS would consider all relevant documentation provided when determining whether to impose a civil money penalty, including information from the complainant, provider (including a provider of air ambulance services), or facility. In 45 CFR 150.513(b), HHS proposes that if CMS were to determine that it would impose a civil money penalty, there are several factors that would be considered when determining the amount of such penalty. CMS would consider the nature of claims of noncompliance and the circumstances under which such claims were presented. CMS would also consider: the degree of culpability of the provider or facility against which a civil money penalty is proposed; the provider or facility's history of prior violations, including whether CMS or any state previously found the provider or facility liable for civil or administrative sanctions in connection with a violation of PHS Act requirements or section 106(a) of the No Surprises Act, as applicable; the frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread; and the level of financial and other impacts on affected

individuals. CMS would also consider any other matters as justice may require.

In 45 CFR 150.513(c), HHS proposes that for every violation subject to a civil money penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty would be set at an amount sufficiently below the statutory maximum of \$10,000 to reflect the mitigating circumstance. As guidelines for considering the circumstances listed earlier, CMS would consider several factors as mitigating circumstances. First, CMS would consider the provider or facility's record of prior compliance. If, for example, the provider or facility implemented and followed a compliance plan before receipt of the notice of potential noncompliance, implementing and following such compliance plan would be considered a mitigating circumstance. If the provider or facility had no previous complaints against it for noncompliance, that would also be considered a mitigating circumstance. Second, CMS would consider the gravity of the violation(s). For example, it would be considered a mitigating circumstance if the provider or facility made adjustments to its business practices to come into compliance with PHS Act requirements so that the provider or facility: (i) Identified all participants, beneficiaries, and enrollees, or all plans or issuers, that are or were wrongly billed; (ii) withdrew the bill or reimbursed the affected individuals, or plans or issuers, that were wrongly billed so that, to the extent practicable, the affected individuals, plans or issuers are in the same position that they would have been in had the violation not occurred; and (iii) completed those adjustments to its business practices in a timely manner. Finally, it would be considered a mitigating circumstance if the provider or facility demonstrated that the violation was an isolated occurrence.

HHS also proposes in 45 CFR 150.513(d) that CMS would consider certain factors to be aggravating circumstances. HHS proposes that for every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS may set the aggregate amount of the penalty at an amount sufficiently close to or at the \$10,000 permitted by statute to reflect that fact. If the frequency of violation indicates a pattern of widespread occurrence, that would be considered an aggravating circumstance. If the violation(s) resulted in significant financial and other impacts on the average affected individual(s), plan or issuer, that would also be considered an

aggravating circumstance. Finally, if the provider or facility does not provide documentation showing that substantially all of the violations were corrected, that would be considered an aggravating circumstance.

In 45 CFR 150.513(e), HHS proposes that if certain criteria are met, CMS would waive a penalty. Section 2799B-4(b)(4) of the PHS Act provides that HHS will waive a civil money penalty if the provider or facility does not knowingly violate, and should not have reasonably known it violated, sections 2799B-1 and 2799B-2 of the PHS Act or, in the case of a provider of air ambulance services, section 2799B-5 of the PHS Act, as long as the provider or facility withdraws any erroneous bill and, if necessary, reimburses the plan or enrollee, within 30 days of the violation in an amount equal to the difference between the amount billed and the amount allowed to be billed, plus interest at a rate determined by the Secretary. HHS proposes that the interest rate be the rate established by the Treasury pursuant to 31 U.S.C. 3717. That is the rate HHS customarily uses for overpayments and underpayments.³⁴ The CAA also provides that HHS will waive a civil money penalty in the case of a provider of air ambulance services that submits only part of the data required in section 106(a) of the No Surprises Act, if such provider demonstrates a good faith effort in working with HHS to submit any missing information. HHS proposes to codify that waiver language in 45 CFR 150.513(e)(2).

In 45 CFR 150.513(f), HHS proposes that nothing in this proposed section limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with 45 CFR 150.505 or to compromise on any penalty provided for in 45 CFR 150.515. This is consistent with the settlement authority described in 45 CFR 150.325.

HHS recognizes that there may be certain circumstances in which imposition of a civil money penalty would create a significant financial hardship for a provider or facility. Various circumstances may give rise to

³⁴ See 42 CFR 405.378 which provides that the interest rate on overpayments and underpayments is the higher of: (i) The rate as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of final determination as defined in paragraph (c) of this section; or (ii) The current value of funds rate (this rate is published annually in the **Federal Register** by the Secretary of the Treasury, subject to quarterly revisions). See also 45 CFR 30.18(b)(2) which provides "unless a different rate is prescribed by statute, contract, or a repayment agreement, the rate of interest charged shall be the rate established annually by the Secretary of the Treasury pursuant to 31 U.S.C. 3717."

financial hardship, potentially including the financial impact of natural disasters or public health emergencies, provider disability or death, and provider solvency concerns. The No Surprises Act allows HHS to establish a hardship exemption to the civil money penalties that would otherwise be imposed for a violation of Part E of Title XXVII of the PHS Act. HHS proposes to codify the hardship exemption in 45 CFR 150.513(g). HHS seeks comments regarding this proposal, including examples of additional circumstances that may warrant a hardship exemption.

28. Notice of Proposed Determination (45 CFR 150.515)

Section 2799B-4(b)(1) of the PHS Act and section 106(e) of the No Surprises Act require HHS to apply certain subsections of section 1128A of the SSA when imposing a civil money penalty upon a provider or facility. Specifically, section 1128A(c) of the SSA provides that HHS may initiate an action for a civil money penalty by serving notice of the action in any manner authorized under Rule 4 of the Federal Rules of Civil Procedure. HHS proposes to codify that procedural requirement in 45 CFR 150.515 and specify that such written notice would include a description of the requirements that CMS believes the provider or facility has violated; a description of any complaint or other information upon which CMS based its investigation; and the amount of the proposed penalty, including any aggravating or mitigating circumstances described in 45 CFR 150.513 that were considered when determining the amount of the proposed penalty.

HHS proposes that the notice of proposed determination would also include instructions for the provider or facility to respond to the notice, including a specific statement of the provider or facility's right to a hearing and a statement that failure to request a hearing within 30 days of receipt of the notice permits the imposition of the proposed penalty without right of appeal.

29. Hearing (45 CFR 150.517)

Section 2799B-4(b)(1) of the PHS Act and section 106(e)(3) of the No Surprises Act specify that sections 1128A(c)(2) and (c)(4) of the SSA apply to any hearing for a violation of this part. Section 1128A(c)(2) of the SSA requires HHS to provide written notice and an opportunity for an adverse determination to be made on the record after a hearing at which the provider or facility is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses.

Section 1128A(c)(4) of the SSA allows the official conducting the hearing to sanction a person, including any party or attorney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct that would interfere with the speedy, orderly, or fair conduct of the hearing. Any such sanctions must reasonably relate to the severity and nature of the failure or misconduct and may include: (a) In the case of refusal to provide or permit discovery, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established; (b) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense; (c) striking pleadings, in whole or in part; (d) staying the proceedings; (e) dismissal of the action; (f) entering a default judgment; (g) ordering the party or attorney to pay attorneys' fees and other costs caused by the failure or misconduct; and (h) refusing to consider any motion or other action which is not filed in a timely manner.

Most of these requirements regarding hearings, insofar as they apply to hearings conducted under 45 CFR part 150, subpart E, are codified in various sections of 45 CFR part 150, subpart D; and in these proposed rules HHS is additionally proposing amendments to 45 CFR 150.401, 150.405, 150.417, 150.445, and 150.455 to conform to these requirements. Therefore, HHS proposes in 45 CFR 150.517 to specify that the provisions in 45 CFR 150.401 through 150.457 apply to a hearing conducted under 45 CFR part 150, subpart E.

HHS proposes in 45 CFR 150.517(b) that if CMS finds a provider or facility to be in violation of a requirement of Part E of Title XXVII of the PHS Act, or section 106(a) of the No Surprises Act, such provider or facility has a right to a hearing pursuant to section 1128A(c)(2) of the SSA. HHS proposes that the provider or facility would be required to file a request for hearing within 30 days after the date of receipt of CMS's notice of proposed determination, to facilitate a timely resolution of the matter.

HHS proposes in 45 CFR 150.517(c) that, consistent with 45 CFR 150.347 as it applies to non-Federal governmental plans and issuers, if the provider or facility fails to request a hearing within the 30 days, any penalty would become final.

30. Failure To Request a Hearing (45 CFR 150.519)

HHS proposes in 45 CFR 150.519 that if the provider or facility does not request a hearing within 30 days of the issuance of the notice of proposed determination, or show good cause, as determined under 45 CFR 150.405(b) for failing to exercise its right to a hearing, the determination becomes final, and CMS would notify the provider or facility of this fact, and the final civil money penalty may be assessed by CMS. CMS would notify the provider or facility in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of the means by which the provider or facility may satisfy the judgment. HHS further proposes that the provider or facility would have no right to appeal a penalty with respect to which it has not requested a hearing in accordance with 45 CFR 150.405. This aligns with CMS's enforcement procedures when an issuer or non-Federal governmental plan fails to request a hearing.

31. Collateral Estoppel (45 CFR 150.521)

Section 1128A(c)(3) of the SSA states that a provider or facility that requests a hearing under this part may not deny the essential elements of a criminal offense if that provider or facility has been convicted of a Federal crime charging fraud or false statements (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) and the hearing under this part involves the same transaction as the criminal action. HHS proposes to codify that statutory language in 45 CFR 150.521.

32. Judicial Review (45 CFR 150.523)

HHS proposes in 45 CFR 150.523 that any responsible provider or facility against which a final decision imposing a civil money penalty is entered pursuant to this subpart may obtain review in the United States Court of Appeals for the circuit in which the person resides, or where the violation occurred, by filing in such court (within 60 days following the date on which such decision becomes final) a written petition requesting the decision be modified or set aside. Such review would be conducted pursuant to section 1128A of the SSA. A copy of the petition would be transmitted by the clerk of the court to CMS, and thereupon CMS would file in the Court the record in the proceeding as provided in 28 U.S.C. 2112.

33. Notice to Other Agencies (45 CFR 150.525)

At 45 CFR 150.525, HHS proposes that whenever a penalty becomes final, CMS would notify certain organizations and entities about such action and the reasons for it, as appropriate. Section 150.525 lists the organizations or entities that section 1128A(h) of the SSA requires to be notified if a penalty was imposed against a provider or facility: The state or local medical or professional association, the state Department of Health, the appropriate state or local licensing agency or organization, and the appropriate utilization and quality control peer review organization. HHS proposes that CMS may additionally notify the following agencies by providing the final penalty notice, as appropriate: The state Department of Insurance or similar agency, the state Attorney General, the DOL, the Department of the Treasury, or OPM by sharing the final penalty notice. HHS seeks comment on any other organizations or entities that should be notified if a provider or facility is penalized for a violation of the PHS Act or a violation of section 106(a) of the No Surprises Act.

IV. Provisions of the Proposed Rules on Reporting Requirements Regarding Air Ambulance Services—Office of Personnel Management

OPM proposes requirements related to data collection from FEHB carriers with respect to air ambulance services provided to covered individuals in an FEHB plan in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage. The OPM rules would clarify that FEHB carriers are both authorized and required by OPM to report information on air ambulance claims data to HHS in accordance with the requirements of 45 CFR 149.230. OPM would coordinate with HHS to receive FEHB air ambulance data. This data would be used by both HHS in its report to Congress and by OPM in its oversight of the FEHB Program.

Under 5 U.S.C. 8902(p), FEHB carriers must comply with requirements described in section 9817 of the Code, section 717 of ERISA, and section 2799A–2 of the PHS Act in the same manner as those provisions apply to group health plans and health insurance issuers offering group or individual health insurance coverage. Similarly, 5 U.S.C. 8902(p) applies balance billing protections described in section 2799B–5 of the PHS Act to enrollees in an FEHB plan in the same manner as those

provisions apply to enrollees in a group health plan or coverage offered by an issuer. Despite these parallel provisions, 5 U.S.C. 8902(p) does not reference the reporting requirements found in section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act.

Under 5 U.S.C. 8910(a), OPM must make a continuing study of the operation and administration of the FEHB Program, including reports on FEHB plans' experience. Under 5 U.S.C. 8910(b), each contract between OPM and FEHB carriers must contain provisions requiring carriers to furnish such reasonable reports as OPM deems necessary to carry out its functions under the FEHB Act. Accordingly, OPM's contract with each FEHB carrier requires the carrier to furnish reports that OPM finds necessary to properly administer the FEHB Program.³⁵ In addition, 5 U.S.C. 8910(c) requires government agencies to furnish OPM with such information and reports as may be necessary to enable OPM to administer the FEHB Program.

Enactment of 5 U.S.C. 8902(p) extends new surprise billing protections with respect to air ambulance services to FEHB plan enrollees and their covered family members. OPM has determined that in order to effectively carry out its functions under 5 U.S.C. 8902(p), including the underlying goals of increased transparency and lowered costs for FEHB covered individuals, carriers must furnish to HHS air ambulance data as provided for in this proposed rule.

FEHB covered individuals utilize air ambulance services not only domestically but also to transport Federal civilian personnel back to the United States from service performed overseas, in the case of medical emergencies. OPM currently lacks comprehensive information with respect to air ambulance services and claims, and this data could prove important to OPM as it negotiates benefits and rates with carriers pursuant to 5 U.S.C. 8902 as well as relative to its general administration and oversight of the FEHB Program.

OPM maintains authority to study the experience of plans and to require carriers to furnish reports that OPM determines necessary pursuant to 5 U.S.C. 8910, and this may include reports that OPM authorizes as necessary to be submitted to HHS where

³⁵ In addition to this statutory authority and parallel contract language, FEHB carrier contracts incorporate FEHB regulations found at 5 CFR parts 890 through 894. As part of this proposed rulemaking, OPM proposes to amend FEHB regulations to direct carriers to comply with requirements of 45 CFR 149.230.

OPM deems those reports important in support of the FEHB mission. Further, 5 U.S.C. 8910(c) authorizes HHS to share data with OPM that is necessary for OPM's study and oversight of the FEHB Program. For these reasons, OPM proposes to authorize and require FEHB carriers to submit air ambulance data to HHS. OPM would coordinate with HHS to receive FEHB air ambulance services data for its administrative and oversight functions of the FEHB Program under 5 U.S.C. 8910. OPM would enforce carrier compliance with reporting requirements to HHS with respect to FEHB plans. OPM would enforce compliance through its contracts with the carriers.

OPM understands the need to ensure stakeholder and consumer privacy when data is shared with OPM. HHS has taken steps to ensure that claims-level data elements would be limited. OPM would collect and store any data it receives through IT systems that meet all security protocols established by OPM. When using these data, OPM would de-identify and aggregate data to protect the confidentiality of proprietary and personal information.

OPM requests comment on its proposal to require air ambulance services claims data to be reported by FEHB carriers to HHS and for HHS to share this data with OPM.

V. Collection of Information Requirements—The Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (PRA), the Departments are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. These proposed rules contain information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 7. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments seek comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the agencies.
- The accuracy of the Departments' estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the

affected public, including automated collection techniques.

The Departments are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, HHS generally used data from the Bureau of

Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.³⁶ Table 1 in these proposed rules presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a

rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and HHS is of the view that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 1—WAGE ESTIMATES

| Occupation title | Occupational code | Mean hourly wage (\$/hr.) | Fringe benefits and overhead (\$/hr.) | Adjusted hourly wage (\$/hr.) |
|---|-------------------|---------------------------|---------------------------------------|-------------------------------|
| Computer and Information Systems Managers | 11–3021 | \$77.76 | \$77.76 | \$155.52 |
| Computer Programmers | 15–1251 | 45.98 | 45.98 | 91.96 |
| Secretaries and Administrative Assistants, Except Legal, Medical, and Executive | 43–6014 | 19.43 | 19.43 | 38.86 |
| Business Operations Specialist | 13–1198 | 40.53 | 40.53 | 81.06 |
| Database Administrator | 15–1245 | 48.60 | 48.60 | 97.20 |
| Lawyer | 23–1011 | 71.59 | 71.59 | 143.18 |
| Insurance Sales Agents | 41–3021 | 33.22 | 33.22 | 66.44 |

B. ICRs Regarding Disclosure of Agent and Broker Compensation to Individuals in Individual Health Insurance Coverage and Short-Term, Limited-Duration Insurance (45 CFR 148.410(c)(2)(i) and (ii) and (c)(3) and (4))

As discussed in section III.B of the preamble of these proposed rules, section 2746 of the PHS Act, as added by section 202(c) of Title II of Division BB of the CAA, requires health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to make disclosures to enrollees regarding direct and indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage, prior to when the individual finalizes their plan selection, as well as on any documentation confirming the individual’s enrollment, including enrollment documentation required in applicable state or Federal law or an initial enrollment package. At new proposed 45 CFR 148.410(c), HHS proposes to codify these disclosure requirements.

HHS assumes that the compensation information to be provided to potential policyholders prior to finalizing enrollment would be provided by agents and brokers on behalf of issuers. As discussed in section III.B of the

preamble of these proposed rules, HHS anticipates the required information would be provided in the form of a commission schedule, a similar document satisfying the requirements of 45 CFR 148.410(c)(5), or a supplemental document detailing additional compensation not on the commission schedule, detailing the compensation structure of agents and brokers who assist consumers in enrolling in and purchasing individual health insurance coverage or short-term, limited-duration insurance. HHS anticipates that the burden associated with the disclosure requirement, prior to implementation, would include review by a lawyer. HHS assumes that a lawyer for each issuer would need 2 hours (at an hourly rate of \$143.18) to review the regulation, and prepare instructions for issuers to relay to individual agents and brokers to implement the disclosure requirements. The burden for each issuer would be 2 hours, with an equivalent cost of approximately \$286. There are an estimated 1,298 issuers in the individual market³⁷ and 26 issuers of short-term, limited-duration insurance coverage,³⁸ for a total of 1,324 issuers. Therefore, the total annual burden to all issuers to implement the disclosure requirement would be 2,648 hours with an equivalent cost of approximately \$379,141. The review of the statute, regulation, and issuer’s implementation

plan would likely occur annually to ensure compliance with any potential changes to the regulation. HHS assumes that each agent or broker would need 30 minutes (at an hourly rate of \$66.44) annually to review the requirements and the instructions from issuers. The total burden for each agent or broker would be 0.5 hours with an equivalent cost of approximately \$33. As of June 10, 2021, there were 55,541 agents or brokers working with issuers and each agent or broker had approximately two appointment arrangements which are mandated by state law and govern the compensation provided to agents and brokers for assisting consumers.³⁹ Therefore, the total burden for all agents and brokers, to review instructions from the issuers with which they have appointment arrangements, would be 27,770.5 hours, with an equivalent cost of approximately \$1,845,072.

HHS estimates the cost associated with this disclosure requirement, when provided in situations related to in-person enrollment in coverage, to be limited to only printing and material costs. HHS estimates that each commission schedule would be, on average, 4 pages in length, at a cost of \$0.05 per page, for a total of \$0.20 per provided schedule. Printing of supplemental documentation disclosing compensation not included on the commission schedule would be, on

³⁶ See May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/oes_nat.htm.

³⁷ Based on data from medical loss ratio (MLR) annual report for the 2019 MLR reporting year, available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

³⁸ National Association of Insurance Commissioners, 2019 Accident and Health Policy

Experience Report. <https://content.naic.org/sites/default/files/publication-ahp-lr-accident-health-report.pdf>.

³⁹ Based on information found in the National Insurance Producer Registry’s Producer Database (PDB).

average, 2 pages in length, at a cost of \$0.05 per page, for a total of \$0.10 per provided supplemental document. HHS assumes, based on experience with the regulation of insurance agents and brokers operating on the Federally-facilitated Exchanges and State-based Exchanges on the Federal Platform, that for most consumers, the information would be provided electronically or orally at minimal cost. HHS assumes that each agent or broker would provide, on average, ten commission schedules

and ten supplemental documents in print to consumers annually from each arrangement, for a total of 20 commission schedules and 20 supplemental documents provided in print. Each agent or broker would incur an annual printing cost of approximately \$6. For all agents and brokers, HHS estimates that a total of 1,110,820 printed commission schedules and 1,110,820 printed supplemental documents would be provided to consumers, for a total

printing cost of \$333,246 annually. HHS assumes that agents and brokers would be compensated by issuers for the printing costs associated with providing the compensation schedules and supplemental documents to consumers. Therefore, HHS estimates that each issuer, on average, would incur printing costs of approximately \$252 annually, starting in 2022. The total costs to all issuers for disclosures provided prior to enrollment, including printing costs, would be approximately \$712,387.

TABLE 2—PROPOSED ANNUAL ONGOING COSTS REGARDING DISCLOSURE OF AGENT AND BROKER COMPENSATION TO ENROLLEES PRIOR TO ENROLLMENT

| Respondent | Estimated number of respondents | Estimated number of responses | Estimated burden (hours) | Estimated labor costs (\$) | Estimated printing costs | Estimated total cost (\$) |
|--------------------------|---------------------------------|-------------------------------|--------------------------|----------------------------|--------------------------|---------------------------|
| Issuer | 1,324 | 1,110,820 | 2,648 | \$379,141 | \$333,246 | \$712,387 |
| Agents and Brokers | 55,541 | 55,541 | 27,771.5 | 1,845,072 | 0 | 1,845,072 |

Issuers would also be required to provide an agent or broker compensation disclosure to individuals on documentation confirming enrollment, including enrollment documentation required by applicable state or Federal law or an initial enrollment package. HHS assumes that the disclosure and supplemental documentation disclosing compensation not included on the commission schedule provided along with documentation confirming enrollment would be available to all enrollees in the same coverage, in the same household, via the policyholder receiving the disclosure information and informing all enrollees on the plan. There are an estimated 1,298 issuers in the individual market providing approximately 8,639,866 enrollment confirmations annually, and 26 issuers of short-term, limited-duration insurance providing approximately 121,038 enrollment confirmations annually. HHS assumes that 50 percent of policyholders with individual health insurance coverage⁴⁰ and all policyholders with short-term, limited-duration insurance are assisted by agents or brokers.

In the individual market, 1,298 issuers would be required to provide commission schedules or similar documentation, and supplemental documentation detailing the structure for compensation not captured on the

commission schedule, along with approximately 4,319,933 enrollment confirmations, 3,328 on average per issuer. HHS estimates that approximately 66 percent of commission schedules and supplemental documents (2,851,156 disclosures) would be mailed to individuals (34 percent sent electronically)⁴¹ in conjunction with any documents confirming enrollment or renewal notice with no additional mailing costs. Therefore, each issuer would provide approximately 2,197 commission schedules or similar documentation, as well as the supplemental documents by mail annually. HHS assumes that for each issuer, an administrative assistant would need 5 minutes (at an hourly rate of \$38.86) to print and enclose a commission schedule or similar documentation, as well as the supplemental document, with the enrollment confirmation or renewal notice, for a cost of \$3.24 per commission schedule or similar documentation, and the supplemental documentation. The total burden for each issuer would be approximately 183 hours, with an equivalent cost of approximately \$7,113 annually. For all issuers, the total annual burden would be 237,596 hours with an equivalent cost of approximately \$9,232,993. Assuming that the cost of printing each commission schedule or similar

documentation would be \$0.20, and the cost of printing each supplemental document would be \$0.10, the average cost of printing for each issuer would be approximately \$659 annually and the total cost of printing for all issuers would be approximately \$855,347. The total annual cost for all issuers, including printing costs, would be \$10,088,340.

For short-term, limited-duration insurance, 26 issuers would be required to provide commission schedules or similar documentation, as well as supplemental documentation detailing the structure for compensation not captured on the commission schedule, along with approximately 121,038 enrollment confirmations, 4,655 on average per issuer. HHS estimates that approximately 66 percent of commission schedules or similar documentation, and supplemental documents (79,885 disclosures) would be mailed to individuals in conjunction with any documents confirming enrollment or renewal notice with no additional mailing costs. Therefore, each issuer would provide approximately 3,073 commission schedules or similar documentation, and supplemental documentation, by mail annually. HHS assumes that for each issuer, an administrative assistant would need 5 minutes (at an hourly rate of \$38.86) to print and enclose a commission schedule or similar documentation, and the supplemental documentation, with the enrollment confirmation or renewal notice, for a cost of \$3.24 per disclosure. The total burden for each issuer would be approximately 256 hours, with an equivalent cost of approximately \$9,950

⁴⁰ Agents and brokers accounted for 47.8 percent of all consumers enrolled during the plan year 2020 open enrollment period. Source: CMS, Agents and Brokers in the Marketplace. <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Agents-and-Brokers-in-the-Marketplace.pdf>.

⁴¹ According to data from the National Telecommunications and Information Agency, 34 percent of households in the United States accessed health records or health insurance online. <https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show>.

annually. For all issuers, the total annual burden would be 6,657 hours with an equivalent cost of approximately \$258,695. Assuming that the cost of printing each commission schedule or similar documentation would be \$0.20, and the cost of printing each supplemental document would be \$0.10, the average cost of printing for each issuer would be approximately \$35

annually and the total printing cost for all issuers would be \$922. The total annual cost for all issuers, including printing costs would be \$259,616.

For issuers of individual health insurance coverage or issuers of short-term, limited-duration insurance, the total combined burden for providing disclosures and supplemental documents with enrollment materials

would be 244,253 hours, with an equivalent cost of \$9,491,687. The total annual printing cost would be \$856,268, with an overall annual total cost of \$10,347,956. CMS is seeking an OMB control number and approval for the proposed information collection (OMB control number: 0938–NEW (Agent and Broker Disclosure and Reporting Requirements (CMS–10787))).

TABLE 3—PROPOSED ANNUAL ONGOING COSTS RELATED TO AGENT AND BROKER COMPENSATION DISCLOSURE PROVIDED WITH ENROLLMENT MATERIALS

| Type of coverage | Estimated number of respondents | Estimated number of responses | Total burden (hours) | Estimated labor cost | Estimated printing cost | Estimated total cost |
|--|---------------------------------|-------------------------------|----------------------|----------------------|-------------------------|----------------------|
| Individual health insurance coverage | 1,298 | 4,319,933 | 237,596 | \$9,232,993 | \$855,347 | \$10,088,340 |
| Short-term, limited-duration insurance | 26 | 121,038 | 6,657 | 258,695 | 922 | 259,616 |
| Total | 1,324 | 4,440,971 | 244,253 | 9,491,687 | 856,268 | 10,347,956 |

C. ICRs Regarding Issuer Requirements for Agent and Broker Compensation Reporting to the Secretary of HHS (45 CFR 148.410(d))

As discussed in section III.B of the preamble, section 2746 of the PHS Act, as added by section 202(c) of Title II of Division BB of the CAA, requires health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to submit reports to HHS regarding direct and indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage. HHS is proposing to codify these reporting requirements in new proposed 45 CFR 148.410(d).

HHS estimates that each issuer would incur an annual ongoing burden and cost to submit the required information annually to HHS, starting in 2023 (reporting for calendar year 2022 would be due by July 31, 2023). HHS acknowledges that the burden associated with this reporting requirement would vary depending on the size of the issuer. HHS estimates that for each issuer, on average, an administrative assistant would need 10 hours (at an hourly rate of \$38.86) and a database administrator would need 40 hours (at an hourly rate of \$97.20) to collect and submit the required information, as described in section III.B of the preamble, electronically. HHS

estimates that each issuer would incur an annual ongoing burden of 50 hours, with an associated equivalent cost of \$4,277. For all 1,324 issuers, HHS estimates a total annual ongoing burden of 66,200 hours and an associated total annual cost of \$5,662,218. HHS believes the burden and costs would decrease in subsequent years as issuers become more adept at extracting the data from their systems and submitting it to HHS. CMS is seeking an OMB control number and approval for the proposed information collection (OMB control number: 0938–NEW (Agent and Broker Disclosure and Reporting Requirements (CMS–10787))).

TABLE 4—PROPOSED ANNUAL ONGOING COSTS REGARDING ISSUER REPORTING OF AGENT AND BROKER COMPENSATION TO HHS

| Estimated number of respondents | Estimated number of responses | Burden per response (hours) | Total estimated annual burden (hours) | Total estimated labor cost |
|---------------------------------|-------------------------------|-----------------------------|---------------------------------------|----------------------------|
| 1,324 | 1,324 | 50 | 66,200 | \$5,662,218 |

D. ICRs Regarding Air Ambulance Reporting Requirements for Group Health Plans and Health Insurance Issuers (45 CFR 149.230)

As discussed in section II.E of the preamble, section 106(b) of the No Surprises Act added parallel provisions at section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act, requiring plans and issuers to submit certain data related to air ambulance services for dates of service falling within a calendar year and data on claims paid within the calendar year. In this proposed rule, OPM also proposes to direct FEHB carriers to

comply with requirements of 45 CFR 149.230 with respect to an FEHB plan in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage. The proposed time and manner of the reporting are set forth in 45 CFR 149.230(a) of these proposed rules, and 45 CFR 149.230(b) includes a list of the data elements the Departments propose to collect on air ambulance services from plans, issuers, and FEHB carriers. The Departments and OPM assume that TPAs generally would incur the burden to submit the data on behalf of self-

insured plans and the associated costs would likely be passed on to those plans. The Departments and OPM acknowledge that some large self-insured plans may seek to make needed IT changes and report the required information to HHS without the use or assistance of a TPA or other third-party entity. In those instances, the self-insured plan would directly incur the burden and cost to meet the requirements of these proposed rules. The Departments and OPM are unable to determine how many self-insured plans may choose to develop their IT system and report the required

information to HHS and seek comment as to the number of plans that may choose to do so.

Issuers, FEHB carriers, and TPAs (and any self-insured plans that choose not to use a TPA or third-party entity to make the appropriate IT and system changes) would incur burdens to make IT changes to collect, consolidate, and report the required information, in the required format, to HHS. The Departments and OPM assume this one-time cost would be incurred in 2022. The Departments and OPM estimate that 473 issuers, 46 FEHB carriers, and 205 TPAs would be subject to the requirements in these proposed rules. The Departments and OPM estimate that for each issuer, FEHB carrier, or TPA to make the appropriate IT changes and submit the required data, it would take a computer and systems information manager 8 hours (at an hourly rate of \$155.52) to design and direct the work required for the updates, and a computer programmer 40 hours (at an hourly rate of \$91.96) to collaborate with the manager to design and implement system changes. The Departments and OPM estimate each issuer, FEHB carrier, or TPA would incur a one-time burden of 48 hours, with an equivalent cost of \$4,923. For all issuers, FEHB carriers, and TPAs to

meet the proposed reporting requirements, the Departments and OPM estimate a total one-time burden of 34,752 hours, with an equivalent cost of \$3,563,933, to be incurred in 2022.

Once the process for collecting and formatting the required data is established, the Departments and OPM assume that the resources needed to submit the required information for the 2022 and 2023 plan years (to be submitted by March 31, 2023 and March 30, 2024, respectively) would be limited. The Departments estimate that each issuer, FEHB carrier, or TPA would require a computer and systems information manager 4 hours (at an hourly rate of \$155.52) to oversee the compilation of the data, a computer programmer 4 hours (at an hourly rate of \$91.96) to extract the required data and provide it in the required reporting format, and an administrative secretary 4 hours (at an hourly rate of \$38.86) to assemble the documents and submit them to HHS. The Departments and OPM estimate that each issuer, FEHB carrier, or TPA would incur an annual burden of 12 hours, with an equivalent cost of \$1,145. For all issuers, FEHB carriers, and TPAs, the Departments and OPM estimate an annual burden of 8,688 hours, with an equivalent cost of

approximately \$829,241, to be incurred in 2023 and 2024.

The total annual burden for all issuers, FEHB carriers, and TPAs to make the appropriate IT and system changes would be approximately 34,752 hours, at a total cost of approximately \$3,563,933 to be incurred in 2022. Issuers, FEHB carriers, and TPAs would also incur an annual burden, in 2023 and 2024, of 8,688 hours and a total cost of approximately \$829,241 to submit the data to HHS. The total annual burden for all respondents is likely overestimated because the estimate does not reflect process efficiencies for FEHB carriers that are also issuers. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately 15,638 hours in 2022 with an equivalent cost of \$1,603,770 and an annual burden of approximately 3,910 hours in 2023 and 2024, with an equivalent cost of \$373,158. CMS is seeking an OMB control number and approval for the proposed information collection (OMB control number: 0938-NEW (Reporting Requirements Regarding Air Ambulance Services (CMS-10785)). DOL, the Department of the Treasury, and OPM will submit their burden estimates upon approval.

TABLE 5—PROPOSED ONE-TIME AND ANNUAL BURDEN AND COSTS FOR ISSUERS AND TPAs RELATED TO AIR AMBULANCE DATA REPORTING REQUIREMENTS

| Year | Estimated number of respondents | Estimated number of responses | Burden per response (hours) | Total estimated annual burden (hours) | Total estimated labor cost (\$) |
|--------------------------|---------------------------------|-------------------------------|-----------------------------|---------------------------------------|---------------------------------|
| 2022 | 326 | 326 | 48 | 15,638 | \$1,603,770.05 |
| 2023 | 326 | 326 | 12 | 3,910 | 373,158.29 |
| 2024 | 326 | 326 | 12 | 3,910 | 373,158.29 |
| Three-year average | 326 | 326 | 24 | 7,819 | 783,362 |

E. ICRs Regarding Air Ambulance Reporting Requirements for Providers of Air Ambulance Services (45 CFR 149.460)

As described in section II.F of the preamble, section 106(a) of the No Surprises Act requires providers of air ambulance services to submit cost and organizational data as well as other transport-level data related to air ambulance services. In 45 CFR 149.460(a) of these proposed rules, HHS sets forth the proposed time and manner of reporting, and in 45 CFR 149.460(b), HHS lists the data elements HHS proposes to collect on air ambulance services from providers of air ambulance services. HHS estimates the

burden associated with the data reporting required at 45 CFR 149.460 to be the time and effort necessary for providers of air ambulance services to submit the required data elements, in the required format, to HHS.

HHS anticipates a one-time cost for providers of air ambulance services to make IT changes to collect, consolidate, and report the required information, in the required format, to HHS. This one-time cost would be incurred in 2022. HHS estimates that 75 providers of air ambulance services⁴² would be subject to the requirements in these proposed

rules. HHS estimates that for each provider to make the appropriate IT changes and submit the required data, it would require a computer and systems information manager 80 hours (at an hourly rate of \$155.52) to design and direct the work required for the updates, a computer programmer 240 hours (at an hourly rate of \$91.96) to collaborate with the manager to design and implement system changes, and a business operations specialist 80 hours (at an hourly rate of \$81.06) to provide input regarding the data content for the reports. HHS estimates each provider of air ambulance services would incur a one-time burden of 400 hours, with an equivalent cost of \$40,997. For all providers of air ambulance services to

⁴² Fact Sheet—FAA Initiatives to Improve Helicopter Air Ambulance Safety. (February 20, 2014). Retrieved from https://www.faa.gov/news/fact_sheets/news_story.cfm?newsId=15794.

meet the proposed reporting requirements, HHS estimates a total one-time burden of 30,000 hours, with an equivalent cost of \$3,074,760.

Once the process for collecting and formatting the required data is established, HHS assumes that the resources required to submit the required information to HHS for the 2022 and 2023 plan years (to be submitted by March 31, 2023 and March 30, 2024, respectively) would be limited. HHS estimates that each provider of air ambulance services would require a computer and systems information manager 4 hours (at an hourly rate of \$155.52) to oversee the compilation of the data, a computer

programmer 4 hours (at an hourly rate of \$91.96) to extract the required data and provide it in the required reporting format, a business operations specialist 8 hours (at an hourly rate of \$81.06) to review the data reports, and an administrative secretary 4 hours (at an hourly rate of \$38.86) to assist in the assembly of documents and submit them to HHS. HHS estimates that each provider of air ambulance services would incur an annual burden of 20 hours, with an equivalent cost of \$1,794. For all providers of air ambulance services, HHS estimates an annual burden of 1,500 hours, with an equivalent cost of \$134,538 in 2023 and 2024.

The total one-time burden and costs, to be incurred in 2022, for all providers of air ambulance services to make the appropriate IT and system changes would be approximately 30,000 hours and a total cost of approximately \$3,074,760. Providers of air ambulance services would also incur an annual burden and cost to submit the data to HHS, for 2023 and 2024, of 1,500 hours and \$134,538. CMS is seeking an OMB control number and approval for the proposed information collection (OMB control number: 0938–NEW (Reporting Requirements Regarding Air Ambulance Services (CMS–10785))).

TABLE 6—PROPOSED ONE-TIME AND ANNUAL BURDEN AND COSTS RELATED TO AIR AMBULANCE DATA REPORTING REQUIREMENTS FOR PROVIDERS OF AIR AMBULANCE SERVICES

| Year | Estimated number of respondents | Number of responses | Burden per response (hours) | Total annual burden (hours) | Total cost |
|--------------------------|---------------------------------|---------------------|-----------------------------|-----------------------------|-------------|
| 2022 | 75 | 75 | 400 | 30,000 | \$3,074,760 |
| 2023 | 75 | 75 | 20 | 1,500 | 134,538 |
| 2024 | 75 | 75 | 20 | 1,500 | 134,538 |
| Three-Year Average | 75 | 75 | 147 | 11,000 | 1,114,612 |

F. ICRs Regarding CMS Enforcement of Group and Individual Insurance Market and Provider and Facility Requirements (45 CFR 150.303, 150.311, 150.313, 150.509, 150.517, and 150.525)

The process by which CMS investigates allegations of non-compliance against issuers and non-Federal governmental plans is detailed in 45 CFR 150.301 through 150.347. Sections 2799A–1(a)(2)(A)(ii) and 2726(a) of the PHS Act, as amended by the CAA, require CMS to conduct certain targeted audits. Therefore, HHS proposed amendments to 45 CFR 150.303(c) to authorize random and targeted investigation and market conduct examinations.

Section 2723(b) of the PHS Act, as amended by the CAA, authorizes the Secretary of HHS to impose civil money penalties as a means of enforcing the individual and group insurance market requirements contained in Part A and Part D of Title XXVII of the PHS Act with respect to health insurance issuers when a state does not have authority to enforce or fails to substantially enforce these provisions and with respect to group health plans that are non-Federal governmental plans in all states. Section 2799B–4 of the PHS Act, as added by section 104 of the No Surprises Act, adopts a similar framework for CMS’s enforcement authority over providers

and facilities, including providers of air ambulance services, in states that do not have authority or otherwise fail to substantially enforce the requirements of Part E of Title XXVII of the PHS Act, as added by the CAA. In addition, section 106(e) of the No Surprises Act authorizes HHS to impose civil money penalties on providers of air ambulance services for failure to submit to the Secretaries of HHS and Transportation information related to air ambulance services required under section 106(a) of the No Surprises Act.

CMS would take enforcement action upon receiving information that an issuer, non-Federal governmental plan, provider, facility, or provider of air ambulance services may be violating a provision of the PHS Act. Sources of information may include: (i) Complaints; (ii) reports from plans or issuers, providers or facilities, state insurance departments, state health departments, medical boards, the NAIC, and any other Federal or state agencies; and (iii) any other information that indicates potential noncompliance with PHS Act requirements (for example, review of a provider’s or issuer’s public website). Upon receiving information regarding a potential violation where CMS is responsible for enforcement, or upon being selected for a targeted or random investigation or market conduct examination, CMS would undertake

either an investigation or a market conduct examination.

When CMS becomes aware of a potential violation, CMS would commence an investigation by issuing a notice to the responsible entity detailing the potential violation. Such notice would give the responsible entity an opportunity to respond, and state that it may be subject to a civil money penalty or corrective action. HHS proposes that the responsible entity could respond within the allotted time frame (as communicated in the written notice to the responsible entity), request an extension, or default and be subject to the civil money penalty or corrective action. CMS also may subject a provider of air ambulance services to a civil money penalty if such provider fails to submit data required in section 106(a) of the No Surprises Act.

HHS believes this collection is exempt from the PRA under 5 CFR 1320.4(a)(2), which provides an exemption from PRA when information is gathered “during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities.”

G. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 7—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

| Regulation section | OMB control No. | Respondents | Responses | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting | Total labor cost of reporting | Printing and materials cost | Total cost |
|--|-----------------|-------------|-----------|-----------------------------|-----------------------------|--------------------------------|-------------------------------|-----------------------------|------------|
| 45 CFR 148.410(c)(2)(i)— Issuers | 0938—NEW | 1,324 | 1,110,820 | 2 | 2,648 | \$143.18 | \$379,141 | \$333,246 | \$712,387 |
| 45 CFR 148.410(c)(2)(i)— Agents and Brokers | 0938—NEW | 55,541 | 55,541 | 0.5 | 27,771 | 66.44 | 1,845,072 | 0 | 1,845,072 |
| 45 CFR 148.410(c)(2)(ii), 148.410(c)(3) | 0938—NEW | 1,324 | 4,440,971 | 0.06 | 244,253 | 2 | 9,491,687 | 856,268 | 10,347,956 |
| 45 CFR 148.410(d) | 0938—NEW | 1,324 | 1,324 | 50 | 66,200 | 85.53 | 5,662,218 | 0 | 5,662,218 |
| 45 CFR 149.230 | 0938—NEW | 326 | 326 | 24 | 7,819 | 100 | 783,362 | 0 | 783,362 |
| 45 CFR 149.460 | 0938—NEW | 75 | 75 | 146.67 | 11,000 | 101 | 1,114,612 | 0 | 1,114,612 |
| Total | | 59,914 | 5,609,057 | | 359,691 | | 19,276,093 | 1,189,514 | 20,465,607 |

H. Submission of PRA-Related Comments

HHS has submitted a copy of these proposed rules to OMB for its review of the rule’s information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections, please visit CMS’s website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at (410) 786–1326.

HHS invites public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of these proposed rules and identify the rule (CMS–9907–P), the ICR’s CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due November 15, 2021.

VI. Collection of Information Requirements—The Department of Labor, the Department of the Treasury, and OPM

As part of the continuing effort to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. This program helps to ensure that the public understands the Departments’ collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Departments can properly assess the impact of collection requirements on respondents.

Under the PRA, an agency may not conduct or sponsor, and an individual

is not required to respond to, a collection of information unless it displays a valid OMB control number.

The information collections are summarized as follows:

A. ICRs Regarding Air Ambulance Reporting Requirements for Group Health Plans, Health Insurance Issuers, and FEHB Carriers (5 CFR 890.114(e), 26 CFR 54.9823–1, 29 CFR 2590.723)

As discussed in section V.D. of the Collection of Information Requirements for HHS, the total annual burden for all issuers, FEHB carriers, and TPAs (and any self-insured plans that choose not to use a TPA or third-party entity to make the appropriate IT and system changes) would be approximately 34,752 hours, at a total cost of approximately \$3,563,933 to be incurred in 2022. Issuers, FEHB carriers, and TPAs would also incur an annual burden, in 2023 and 2024, of 8,688 hours and a total cost of approximately \$829,241 to submit the data to HHS. As HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, DOL and the Department of the Treasury will each share 25 percent of the burden, and OPM will share five (5) percent of the burden. DOL and the Department of the Treasury will share approximately 8,688 hours in 2022 with an equivalent cost of \$890,983 and an annual burden of approximately 2,172 hours in 2023 and 2024, with an equivalent cost of \$207,310. OPM will share approximately 1,738 hours in 2022 with an equivalent cost of \$1,738 and an annual burden of approximately 434 hours in 2023 and 2024, with an equivalent cost of \$41,462.

Summary of Burden

Type of Review: New Collection.

Agency: DOL—EBSA, Treasury-IRS, OPM—FEHB.

Title: Air Ambulance Reporting Requirements for Group Health Plans,

Health Insurance Issuers, and FEHB Carriers.

OMB Numbers: DOL—1210—NEW, Treasury—1545—NEW.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Total Respondents: 181.

Total Responses: 181.

Frequency of Response: Annually.

Estimated Total Annual Burden Hours: 9,557 (DOL—4,344, Treasury—4,344, OPM—869).

Estimated Total Annual Burden Cost: \$957,423 (DOL—\$870,402, Treasury—\$870,402, OPM—\$87,040).

VII. Response to Comments

Because of the large number of public comments the Departments normally receive on **Federal Register** documents, the Departments are not able to acknowledge or respond to them individually. The Departments will consider all comments received by the date and time specified in the **DATES** section of the preamble, and, when the Departments proceed with a subsequent document, the Departments will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Statement of Need

The proposed reporting requirements in these proposed rules would increase transparency and better understanding regarding agent and broker compensation and the air ambulance industry.

Title II of Division BB of the CAA includes provisions related to increased transparency. The proposed requirements in 45 CFR 148.410 of these proposed rules are related to the agent and broker compensation disclosure and data reporting requirements as set forth in section 202(c) of Title II of Division BB of the CAA. The proposed disclosure requirements would inform consumers of agent and broker compensation prior to enrolling in individual health insurance coverage or short-term,

limited-duration coverage. The proposed reporting requirements would also provide HHS with data for such coverage similar to those collected by the DOL on the compensation provided by issuers of group health insurance coverage.

The proposed requirements in 45 CFR 149.230 and 149.460 of these proposed rules are related to the air ambulance data reporting requirements as set forth in section 106(a) of the No Surprises Act for providers of air ambulance services and section 106(b) of the No Surprises Act, which added parallel provisions at section 9823 of the Code, section 723 of ERISA, and section 2799A–8 of the PHS Act, requiring plans and issuers offering group or individual health insurance coverage to submit claims data related to air ambulance services. The data collection would support the production of the comprehensive report on air ambulance services required under section 106(c) of the No Surprises Act and would enable the identification and analysis of unfair and deceptive practices and unfair methods of competition as noted in section 106(f) of the No Surprises Act. These proposed rules would also implement certain provisions that would allow HHS to enforce the No Surprises Act to protect individuals from surprise medical bills for emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities in certain circumstances.

The proposed revisions to 45 CFR part 150, including the proposed inclusion of a new subpart E, would accomplish three objectives: (i) Implementing section 2799B–4 of the PHS Act, which subjects providers and facilities, including providers of air ambulance services, to CMS enforcement and oversight in certain circumstances; (ii) updating the existing regulations to ensure they align with industry standards and current CMS practices; and (iii) implementing section 106(e) of the No Surprises Act, which states that a provider of air ambulance services that fails to submit all information required under section 106(a)(2) of the No Surprises Act shall be subject to a civil money penalty of not more than \$10,000. The proposed revisions and these new rules are necessary to enable CMS to carry out this statutory mandate and enforce the provisions of the PHS Act and the No Surprises Act against providers and facilities, including providers of air ambulance services. They also serve to strengthen CMS's authority and oversight of issuer and non-Federal governmental plan

compliance with applicable PHS Act requirements.

B. Overall Impact

The Departments have examined the impacts of these proposed rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), 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), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year).

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. An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by OMB. This rule is not likely to have economic impacts of \$100 million or more in at least 1 year, and therefore is not expected to be economically significant under

Executive Order 12866. OMB has determined, however, that the actions are significant within the meaning of section 3(f)(4) of the Executive order. Therefore, the Departments have provided an assessment of the potential benefits and costs associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

The proposed provisions related to disclosure and reporting of direct and indirect agent and broker compensation related to enrollments in individual health insurance coverage and short-term, limited-duration insurance would help provide transparency to consumers wishing to apply for such coverage. The data submitted to HHS by issuers of such coverage would enable HHS to determine the compensation paid to agents and brokers, the structures being used to determine agent and broker compensation, and potentially determine if compensation is being used to intentionally steer individuals toward plans with less comprehensive benefits.

The provisions related to air ambulance data reporting in these proposed rules would provide complete, uniform, nationwide information on air ambulance services that is currently not available. The information collected from providers of air ambulance services would be used to satisfy the requirements for the comprehensive public report described in section 106(c) of the No Surprises Act and to allow the Secretary of Transportation to determine whether a provider of air ambulance services has engaged in unfair and deceptive practices or unfair methods of competition. The data collected from plans and issuers regarding air ambulance services would enable HHS and the Department of Transportation to combine and validate the information collected from plans, issuers, and providers of air ambulance services and would provide additional information to support the production of the report described in section 106(c) of the No Surprises Act. Inclusion of discrete, yet de-identified, air ambulance data from each FEHB carrier will allow for transparency and data validation with respect to air ambulance services provided to FEHB covered individuals, for purposes of ensuring a comprehensive report to Congress, and to further support the implementation of 5 U.S.C. 8902(p) which specifically ends surprise air ambulance bills in the FEHB Program.

In addition, the enforcement provisions in these proposed rules would establish the process by which CMS would investigate complaints and enforce the PHS Act requirements

applicable to non-Federal governmental plans in all states, and issuers, providers, and facilities, including providers of air ambulance services, in states where HHS is directly enforcing PHS Act requirements or in states that are not substantially enforcing the requirements. Furthermore, these provisions detail the process by which CMS would impose civil money penalties against providers and facilities, including providers of air ambulance services, for a violation of an applicable PHS Act provision or for failure to submit required data in compliance with section 106(a) of the No Surprises Act.

Affected entities, such as plans (or third-party administrators on behalf of self-insured group health plans), health insurance issuers, FEHB carriers, issuers of short-term, limited-duration

insurance, providers, including providers of air ambulance services, and facilities would incur costs related to the submission of data on air ambulance services, disclosure and reporting of agent and broker compensation, and enforcement actions. In accordance with Executive Order 12866, the Departments are of the view that the benefits of this regulatory action justify the costs.

C. Impact Estimates and Accounting Table

The provisions in these proposed rules would ensure that plans, issuers, providers (including providers of air ambulance services), and facilities subject to HHS’s enforcement authority comply with requirements in the No Surprises Act and that participants, beneficiaries and enrollees with health care coverage are protected from

surprise medical bills. In addition, having access to information related to agent and broker compensation increases transparency and could help enrollees with individual health insurance coverage and short-term, limited-duration insurance coverage make more informed decisions regarding their health care coverage. In accordance with OMB Circular A–4, Table 8 depicts an accounting statement summarizing the Departments’ assessment of the benefits and costs associated with this regulatory action. The Departments are unable to quantify the benefits of these proposed rules, but have included a qualitative discussion. The effects in Table 8 reflect qualitative impacts and estimated direct monetary costs resulting from the provisions of these proposed rules.

TABLE 8—ACCOUNTING TABLE

Benefits and Intended Outcomes:

Qualitative:

- Increased transparency related to agent and broker compensation arrangements and structures, giving consumers more information as they make choices regarding health care coverage.
- Ability for the Federal Government to analyze and/or investigate potential unfair or deceptive practices against consumers, and unfair methods of competition used by providers of air ambulance services.
- Improved compliance with laws prohibiting surprise medical bills due to enforcement actions.

| Costs: | Estimate (million) | Year dollar | Discount rate (%) | Period covered |
|--------------------------------------|--------------------|-------------|-------------------|----------------|
| Annualized Monetized (\$/year) | \$31.82 | 2021 | 7 | 2021–2025 |
| | 32.35 | 2021 | 3 | 2021–2025 |

Quantitative:

- Costs to issuers of individual health insurance coverage and short-term, limited-duration insurance to provide proposed agent and broker compensation disclosures prior to when an individual finalizes their plan selection, and on any documentation confirming initial enrollment, including enrollment documentation required by applicable state or Federal law or an initial enrollment package estimated to be approximately \$11.1 million annually beginning in 2022.
- Costs to agents and brokers for providing compensation disclosures prior to when an individual finalizes their plan selection, estimated to be approximately \$1.8 million annually beginning in 2022.
- Costs to issuers of individual health insurance coverage and short-term, limited-duration insurance to gather and submit proposed agent and broker compensation data to HHS, expected to be approximately \$5.7 million annually beginning in 2023.
- Costs to plans, issuers, FEHB Carriers, and TPAs to submit proposed air ambulance related information to HHS, estimated to be one-time costs of approximately \$3.6 million in 2022 and annual costs of approximately \$829,241 in 2023 and 2024.
- Costs to providers of air ambulance services to submit proposed information to HHS, estimated to be one-time costs of approximately \$3 million in 2022 and annual costs of approximately \$134,538 in 2023 and 2024.
- Costs to providers and facilities, including providers of air ambulance services, related to enforcement actions, estimated to be approximately \$850,320 annually, starting in 2022.
- Costs to the Federal Government to implement the proposed reporting requirements and enforcement activities, estimated to be \$4 million in 2021, \$20.3 million in 2022, \$22.2 million in 2023, \$18.3 million in 2024 and \$18.4 million in 2025.

Quantitative:

- Potential reduction in income for agents and brokers and potential costs and reduction in revenue and profits for providers of air ambulance services, if there are changes in consumer behavior and operational changes as a result of greater transparency regarding agent and broker compensation and the air ambulance industry.

1. Background

a. Agent and Broker Compensation

The issue of increasing transparency within the health insurance industry regarding agent and broker compensation has drawn escalating attention in recent years. Part of the

increased need for transparency stems from the expanded availability of short-term, limited-duration insurance coverage.⁴³ Insurance agents or brokers

⁴³ Department of the Treasury, Department of Labor, Department of Health and Human Services, *Short-Term, Limited-Duration Insurance*, 83 FR 38212 (Aug. 3, 2018) (www.govinfo.gov/content/

often receive higher commission rates for enrolling consumers in short-term, limited-duration insurance coverage compared to coverage that meets ACA

[pkg/FR-2018-08-03/pdf/2018-16568.pdf](https://www.federalregister.gov/documents/2018/08/03/2018-16568/pdf)) (final rule).

requirements.⁴⁴ There are concerns agents or brokers could encourage consumers to enroll in short-term, limited-duration insurance coverage due to their high commission rates.⁴⁵ In addition, there are concerns that there may be deceptive practices surrounding the sale of short-term, limited duration insurance.⁴⁶ As described in section III.B of the preamble of this proposed rule, agents and brokers enter into appointment arrangements with health insurance issuers. These arrangements govern compensation provided to agents and brokers for assisting consumers with enrollment in an issuer's policies. The specific compensation arrangement between an issuer and the agent or broker is typically laid out in the commission schedule. Compensation arrangements may also include other types of compensation, such as fees and bonuses. Section 2746 of the PHS Act requires both direct and indirect compensation to be disclosed and taken into account for all requirements herein.

b. Surprise Medical Bills for Air Ambulance Services

The issue of surprise medical bills for air ambulance services has drawn increasing attention from the public as the amounts charged by providers of air ambulance services have risen drastically in recent years and because utilization of air ambulance services frequently results in surprise bills. A study by the GAO analyzed private health insurance claims from 2012 and 2017 to describe the extent to which air ambulance transports are out-of-network.⁴⁷ That study analyzed claims data from approximately 24,100 air ambulance transports in 2012 and another 33,800 transports in 2017 from all 50 states and the District of

Columbia. The study found that in 2012, 75 percent of transports were out-of-network and in 2017, 69 percent were out-of-network. The GAO also reported that the median price charged by providers of air ambulance services had increased from a rate of \$22,100 for rotary-wing and \$24,900 for fixed-wing in 2012 to approximately \$36,400 for rotary-wing and \$40,600 for a fixed-wing transport in 2017. The prices charged in 2017 were an increase of over 60 percent from 2012. A previously published report by the GAO also noted that between 2010 and 2014, the median prices charged by providers of air ambulance services for rotary-wing transports approximately doubled.⁴⁸ Another study found that for one of the largest providers (with a market share of approximately 24 percent) the average charge increased from \$17,262.23 in 2009 to approximately \$50,199.24 by 2016.⁴⁹

As the costs associated with air ambulance transports have continued to increase, the GAO reported that providers of air ambulance services report entering into more network contracts.⁵⁰ However, additional analyses found that many providers of air ambulance services, particularly those not affiliated with a hospital, do not participate in issuer networks and have little incentive to do so, further noting that network participation remains low and provider avoidance of insurance network participation combined with aggressive collection practices has been described as a business strategy of some providers of air ambulance services.⁵¹

A study using 2014 through 2017 data from three large issuers to evaluate the share of air ambulance claims that are out-of-network and the prevalence and magnitude of potential surprise balance

bills found that 77 percent of transports were out-of-network, and approximately 40 percent of transports resulted in potential balance bills. The bills averaged approximately \$19,851 in addition to the standard out-of-network cost sharing, which averaged \$561. The study also found that for out-of-network rotary-wing claims, issuers paid the providers' full billed charges approximately 48 percent of the time, for an average of \$35,733 and that for in-network providers, billed charges were paid in full only 7 percent of the time. The study noted that self-insured plans paid out-of-network claims in full 50 percent of the time, whereas fully-insured plans paid claims in full 38 percent of the time,⁵² indicating that individuals enrolled in self-insured plans were less likely to receive balance bills than individuals enrolled in fully-insured plans.

As states, the Federal Government, oversight agencies, and advocacy groups have examined the issue of air ambulance services and balance billing, it has become clear that there is a lack of comprehensive, national data on air ambulance costs, transports, and contractual arrangements between providers of air ambulance services and group health plans and health insurance issuers. Two GAO reports (2017 and 2019) and the FAA Reauthorization Act of 2018 indicate that it is necessary to collect data to better inform policymakers and consumers about the air ambulance services market. For example, increased transparency regarding the costs to provide air ambulance services and billed and paid amounts for air ambulance services would be beneficial in assessing obstacles to network inclusion and contract negotiations involving providers of air ambulance services. Transparency regarding the number and location of air ambulance bases would enable assessment of the availability of services and competition in the air ambulance marketplace. Finally, a publicly-available report regarding air ambulance services would help to improve policymakers' and consumers' understanding of the air ambulance industry.

c. Enforcement

Section 2723 of the PHS Act provides that states are the primary enforcers of the requirements applicable to issuers that issue, sell, renew, or offer health insurance coverage in the state in the

⁴⁴ See U.S. House of Representatives Committee on Energy and Commerce report "Shortchanged: How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk." Page 43 (stating the average commission rate for short-term, limited-duration insurance plans was 23 percent while the average commission rate for ACA-compliant plans was approximately 2 percent in 2018).

⁴⁵ *Id.* At 38 (stating issuers offering short-term, limited-duration insurance coverage have business practices that incentivize agents and brokers to engage in fraudulent or misleading practices).

⁴⁶ See Health Care Sabotage Online: A Warning to Consumers, October 2019 (<https://www.casey.senate.gov/imo/media/doc/Senator%20Casey%20-%20Health%20Care%20Sabotage%20Online%20FINAL.pdf>).

⁴⁷ GAO (2019) Report to Congressional Committees. Air Ambulance. Available Data Show Privately-Insured Patients Are at Financial Risk (GAO-19-292) available at: <https://www.gao.gov/assets/700/697684.pdf>. The data analyzed included claims from over 50 payors in each year (including both fully- and self-insured plans) and accounted for 110.1 million covered lives in 2012 and 145.0 million covered lives in 2017.

⁴⁸ GAO (2017) Report to the Committee on Transportation and Infrastructure, House of Representatives. Air Ambulance. Data Collection and Transparency Needed to Enhance DOT Oversight. (GAO-17-637) available at: <https://www.gao.gov/assets/gao-17-637.pdf>.

⁴⁹ Consumer Union. Up in the Air: Inadequate Regulation for Emergency Air Ambulance Transportation. Health Policy Report, March 2017.

⁵⁰ GAO (2019) Report to Congressional Committees. Air Ambulance. Available Data Show Privately-Insured Patients Are at Financial Risk (GAO-19-292) available at: <https://www.gao.gov/assets/700/697684.pdf>.

⁵¹ Missouri Department of Insurance, Financial Institutions & Professional Registration. Policy Brief: Health Coverage for Air Ambulance Transportation. January 2019; and New Mexico Office of the Superintendent of Insurance. Air Ambulance Memorial Study Report. January 2017. Available at: <https://www.nmlegis.gov/handouts/ERDT%20083117%20Item%208%20NM%20Superintendent%20of%20Insurance%20Air%20Ambulance%20Memorial%20Study%20Report.pdf>.

⁵² Brown, E.C.F. et al., Out-of-Network Air Ambulance Bills: Prevalence, Magnitude, and Policy Solutions. The Milbank Quarterly, Vol. 98, No. 3, 2020 (pp. 747-774).

individual or group market. If HHS determines that a state has failed to substantially enforce a provision of Title XXVII of the PHS Act, HHS enforces that provision with respect to issuers in the state. HHS further enforces the requirements applicable to non-Federal governmental plans in all states. Any non-Federal governmental plan or any issuer subject to HHS's enforcement authority that fails to comply with an applicable provision of Part A or Part D of Title XXVII is subject to a civil money penalty.

Section 2799B-4 of the PHS Act provides that states are the primary enforcers of the requirements applicable to providers and facilities under Part E of Title XXVII of the PHS Act, including providers of air ambulance services. If HHS determines that a state has failed to substantially enforce an applicable provision, HHS enforces that provision in the state. Any provider or facility, including a provider of air ambulance services, that HHS has determined to be in violation of an applicable provision in Part E of Title XXVII of the PHS Act may be subject to a civil money penalty. Under part 106(e) of the No Surprises Act, any provider of air ambulance services that fails to submit data required in section 106(a) of the No Surprises Act may also be subject to a civil money penalty.

According to researchers at the Center on Health Insurance Reforms, Georgetown University Health Policy Institute, 18 states have adopted comprehensive surprise billing protections, and 15 states have adopted partial protections.⁵³ The state agency responsible for implementing and enforcing these protections vary among states. According to the Center on Health Insurance Reforms, "Some states direct their insurance department to ensure compliance with the law, but while insurance departments have clear jurisdiction over insurance companies, they often lack jurisdiction over providers. Some states may rely on their medical licensing authority or "deceptive trade practice" statutes to enforce requirements on providers; other states may be dependent on the attorney general filing a civil lawsuit against providers who continue to send surprise bills to patients."⁵⁴ States have also identified the State Department of Health as the agency with oversight authority over providers with respect to

surprise billing requirements. Because many of these state laws are relatively new, there is little empirical evidence about the cost to state regulators and the regulated parties subject to the surprise billing protections.

2. Benefits and Intended Outcomes

The provisions of this proposed rule require health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to disclose to policyholders any direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage. The proposed disclosure requirements would improve consumers' awareness by providing information on how agents and brokers are compensated with regard to the coverage sold to those individuals or renewed on behalf of the individuals. In this way, consumers will be able to take this into account as they make decisions about obtaining health coverage. Knowing how much an agent or broker would earn in commissions for selling them health insurance coverage could inform a consumer as to whether an agent's or broker's recommendations or promotions of individual health insurance coverage or short-term, limited-duration insurance is due to a potential conflict of interest. Disclosing this information would provide additional clarity to consumers and help inform whether they want to enroll in, or renew, a particular health insurance coverage. To the extent vulnerable populations, including those with ongoing or prior health conditions, are being encouraged to enroll in short-term, limited-duration insurance,⁵⁵ the proposed disclosure requirements might help these individuals better understand the agent's and broker's motivations and incentives in marketing and recommending such coverage. As short-term, limited-duration insurance is generally exempt from the ACA's individual market consumer protection provisions,⁵⁶ issuers of such coverage can draw in lower-income or healthy individuals by offering lower premiums than plans that offer the ACA consumer protections.⁵⁷ It is important for agents

or brokers to disclose their commissions so individuals can take into account the agent's or broker's potential motivations for encouraging enrollment in a specific type of coverage.

All health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance would be required to report annually to HHS any direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage. HHS would use analysis of this information to monitor the marketing operations and practices of issuers of individual health insurance coverage and short-term, limited-duration insurance and inform future policy-making decisions.

The air ambulance data collection would advance policymakers' and the public's understanding of the air ambulance industry and increase the transparency of the market conditions affecting air ambulance services. In addition, the data collected from providers of air ambulance services may be used by the Secretary of Transportation to investigate potential unfair or deceptive practices used by these providers against consumers as well as potentially unfair methods of competition in the air ambulance service market.

Surprise medical bills result in higher out-of-pocket expenses and cause financial anxiety and medical debt for consumers.⁵⁸ These proposed rules would establish an enforcement process to help ensure plans, issuers, providers, and facilities, including providers of air ambulance services, comply with the provisions of the PHS Act. Without strong Federal oversight and enforcement mechanisms, there would be no practical consequences when providers and facilities, including providers of air ambulance services, fail to comply with the PHS Act in states that are not directly enforcing the applicable requirements. The Federal oversight and enforcement procedures proposed in 45 CFR part 150 would increase provider and facility, compliance with the new surprise

How the Trump Administration's Expansion of Junk Short-Term Health Insurance Plans is Putting Americans at Risk." Page 12 (<https://www.hsdl.org/?view&did=841078>) and House Committee on Energy and Commerce. E&C Investigation Finds Millions of Americans Enrolled in Junk Health Insurance Plans That Are Bad For Consumers & Fly Under the Radar of State Regulators, Press Release (Jun 25, 2020), <https://energycommerce.house.gov/newsroom/press-releases/ec-investigation-finds-millions-of-americans-enrolled-in-junk-health>.

⁵⁸ Garmon C. and Chatock B. One In Five Inpatient Emergency Department Cases May Lead to Surprise Bills, Health Affairs 36, No. 1 (2017): 177-181.

⁵³ Curran, E. U.S. House Investigation Offers New Evidence on the Dangers of Short-Term Plans. CHIRblog, July 9, 2020, <http://chirblog.org/u-s-house-investigation-offers-new-evidence-dangers-short-term-plans/>.

⁵⁶ See, for example, Excepted Benefits; Lifetime and Annual Limited; and Short-Term Limited-Duration Insurance; final rules, 81 FR 75316 at 75317 (October 31, 2016) and Short-Term, Limited Duration Insurance; final rule, 83 FR 38212 at 38213 (August 3, 2018).

⁵⁷ See U.S. House of Representatives Committee on Energy and Commerce report "Shortchanged:

⁵³ See Kona, Maanasa "State Balance-Billing Protections." *The Commonwealth Fund*, 5 February 2021, <https://www.commonwealthfund.org/publications/maps-and-interactive/2021/feb/state-balance-billing-protections>.

⁵⁴ See <https://surprisemedicalbills.chir.georgetown.edu/policy-options/enforcement/>.

billing and transparency requirements in 45 CFR part 149. Compliance with these provisions is necessary to inform future policy that could help reduce financial anxiety and medical debt by reducing surprise medical bills for individuals with health coverage.

3. Costs

Health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance would incur costs to comply with the agent and broker compensation disclosure and reporting requirements set forth in these proposed rules. Issuers would incur annual costs of approximately \$712,387 to provide agent or broker compensation disclosure and supplemental documentation detailing additional compensation not on the commission schedule prior to enrollment and approximately \$10.3 million to provide the disclosure in documentation confirming enrollment, starting in 2022. Additionally, issuers would incur annual ongoing costs of approximately \$5.7 million to collect and submit the required agent and broker compensation and supplemental documentation detailing additional compensation not on the commission schedule information to HHS starting in 2023. Agents and brokers would incur annual costs of approximately \$1.8 million to provide agent or broker compensation disclosure and supplemental documentation detailing additional compensation not on the commission schedule prior to enrollment beginning in 2022. These costs are discussed in detail in the Collection of Information Requirements section of the preamble.

Issuers, FEHB Carriers, TPAs, and providers of air ambulance services would incur costs to comply with the air ambulance services reporting requirements set forth in these proposed rules. The Departments estimate that 473 issuers, 46 FEHB carriers, and 205 TPAs would incur one-time costs of approximately \$3.6 million in 2022 and annual costs of approximately \$829,241 in 2023 and 2024 to comply with this requirement. These total costs are likely overestimated because the estimate does not reflect process efficiencies for FEHB carriers that are also issuers. In addition, 75 providers of air ambulance services would incur one-time costs of approximately \$3 million in 2022 and annual costs of approximately \$134,538 in 2023 and 2024 to comply with the reporting requirement. These costs are discussed in detail in the Collection of Information Requirements section of the preamble.

Increased transparency regarding agent and broker compensation and greater consumer awareness of potential conflicts of interest for agents and brokers might lead fewer consumers to choose short-term, limited-duration insurance if they feel they are being steered toward such plans due to an agent's or broker's financial self-interest. It might also encourage some agents and brokers to avoid such conflicts of interest. This could result in a reduction in income for some agents and brokers. Increased transparency regarding the air ambulance industry might also lead to operational changes for some providers of air ambulance services, such as an increase in the number of participating providers of air ambulance services for plans and reduced charges. Providers of air ambulance services that make any operational changes would incur related costs and might experience a reduction in profits.

Providers and facilities, including providers of air ambulance services, would, on occasion, incur costs related to enforcement actions taken by CMS. When CMS becomes aware of a potential violation of the PHS Act and is responsible for enforcement, CMS would commence an investigation by issuing a notice to the responsible entity detailing the potential violation. Such notice would give the responsible entity an opportunity to respond, and state that it may be subject to a civil money penalty or corrective action. The responsible entity could respond within the allotted time frame, request an extension, or default and be subject to the civil money penalty or corrective action when there is sufficient evidence indicating there is a PHS Act violation. HHS estimates that, on average, CMS would conduct approximately 200 investigations per month, for a total of 2,400 investigations per year, starting in 2022. HHS estimates that for each potential violation being investigated, a medical secretary would need 3 hours on average (at a rate of \$37.50 per hour) and a manager would need 2 hours on average (at a rate of \$120.90 per hour) to prepare a response and collect supporting documents and submit them to CMS.⁵⁹ The cost for each responsible entity subject to a CMS investigation is estimated to be approximately \$354 for each investigation. The total annual cost

⁵⁹ See May 2020 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/oes_nat.htm. Medical Secretaries and Administrative Assistants (43-6013) \$18.75 * 2 = \$37.50 * 3 hours = \$112.50 and General and Operations Manager (11-1021) \$60.45 * 2 = \$120.90 * 2 = \$241.80. Total cost, \$112.50 + \$241.90 = \$354.30.

related to all 2,400 investigations would be approximately \$850,320. HHS anticipates that the number of investigations and the associated costs would decrease over time as compliance improves.

CMS would review the response provided by the responsible entity and determine if the entity violated a provision of the PHS Act. HHS proposes that if CMS determines that the responsible entity did violate a provision of the PHS Act, then it may impose civil money penalties not to exceed \$10,000 per violation. If CMS determines that a provider of air ambulance services failed to submit information required in section 106(a) of the No Surprises Act by the due date, including any extensions granted, then it may impose civil money penalties not to exceed \$10,000. If the responsible entity timely files a request for appeal, such appeal would be heard before an administrative law judge, who would conduct any appeal as provided in 45 CFR 150.401 through 150.465. Finally, HHS proposes that a responsible entity can appeal the decision of an administrative law judge to the United States Court of Appeals for the district where the provider, facility, or provider of air ambulance services is located or the violation occurred. At this time, HHS is unable to estimate the number of responsible entities that would appeal a penalty or the decision of an administrative law judge and the associated cost.

In addition, the Federal Government would incur costs to build and maintain IT systems to receive, store, and analyze agent and broker compensation data and air ambulance data. In addition, the Federal Government would incur costs related to enforcement of the PHS Act, such as enforcement of reporting requirements for issuers and providers of air ambulance services, conducting compliance reviews of provider and facility websites, review of complaints received, and investigating instances of potential violations of the PHS Act by providers and facilities, including providers of air ambulance services, in states where HHS is directly enforcing PHS Act requirements. The Departments estimate that the total costs associated with these activities would be \$4 million in 2021, \$20.3 million in 2022, \$22.2 million in 2023, \$18.3 million in 2024, and \$18.4 million in 2025.

D. Regulatory Alternatives Considered

In developing the policies contained in these proposed rules, the Departments considered various alternatives to the presented proposals.

In determining the disclosure and data reporting requirements for agent and broker compensation in these proposed rules, HHS considered requiring disclosure of intermediary payments to consumers (for example, payments made through general line agencies or marketing organizations) prior to finalizing enrollment. That level of detail was determined to be impractical and would not have enough positive impact on the consumer to justify the cost to implement. HHS also considered requiring the disclosure of actual amounts of compensation an agent or broker would receive. That, too, was rejected as being impossible to calculate ahead of time, as well as being potentially overly burdensome on the sales process. Furthermore, HHS considered requiring signed documentation from the consumer stating disclosure had occurred. This was not pursued, given concerns regarding burden.

In determining the data reporting requirements for air ambulance services contained in these proposed rules, the Departments considered available alternative regulatory proposals. Given the statutory requirements of section 106 of the No Surprises Act, these alternatives were limited to reducing the number of data reporting elements required. However, collecting data in a more aggregated format would not support many of the analyses required in the statute for the comprehensive report on air ambulance services required under section 106(c). Section 106(c) of the No Surprises Act requires, among other analyses, assessments of amounts paid by issuers for furnishing air ambulance services, amounts paid out-of-pocket by consumers, any changes in the amounts paid over time and as an assessment of any evidence of gaps in rural access to air ambulance services. The absence of detailed transport-level data would limit the Secretaries' of HHS and Transportation ability to conduct these analyses.

E. Regulatory Flexibility Act

The RFA (5 USC 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of these proposed rules 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." HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

The provisions in these proposed rules would affect health insurance issuers, group health plans, TPAs (on behalf of self-insured group health plans), and issuers of short-term, limited-duration insurance. Health insurance issuers and group health plans would be classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$41.5 million or less are considered small entities for this North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$35 million or less.⁶⁰ The Departments expect that few, if any, insurance companies underwriting 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 medical loss ratio (MLR) annual report⁶¹ submissions for the 2019 MLR reporting year, approximately 77 out of 473 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 67 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 \$41.5 million. The Departments are of the view that the same assumptions also apply to TPAs that would be affected by these proposed rules.

Providers of air ambulance services would be classified under NAICS code 621910 (Ambulance Services), with a size standard of \$16.5 million or less. Based on a 2020 USC-Brookings Schaeffer report on air ambulance services,⁶² by 2017, large private equity firms controlled roughly two-thirds of the air ambulance market. The

Departments lack data on the number of small entities in the air ambulance market. As discussed earlier in the Collection of Information Requirements section, a provider of air ambulance services would incur a cost of approximately \$41,000 in 2022 and annual costs of \$1,794 in 2023 and 2024 to submit the required information to HHS. The Departments seek comment on whether any providers of air ambulance services may be considered small entities (including entities with annual revenue under \$16.5 million or independent not-for-profit entities not dominant in the industry) and whether these costs would result in an impact of more than 3 to 5 percent of revenues for those small entities.

Agents and brokers would be classified under NAICS code 524210 (Insurance Agencies and Brokerages), with a size standard of \$8 million or less. The proposed requirement to provide agent or broker compensation disclosure to individuals prior to enrollment would affect an estimated 55,541 agents and brokers, many of whom are likely to be employed by small entities. As discussed earlier in the HHS Collection of Information Requirements section, an agent or broker would incur a cost of approximately \$33 to comply with the proposed requirement. This is unlikely to cause a change in revenue of more than 3 to 5 percent for agents and brokers.

As discussed earlier in the Regulatory Impact Analysis, the proposed provisions related to enforcement in these proposed rules regarding enforcement of section 2799B-4 of the PHS Act would also affect approximately 2,400 providers (including providers of air ambulance services) and facilities annually, some of which might be small entities. A provider or facility subject to investigation would incur a cost of approximately \$354. This is unlikely to cause a change in revenue of more than 3 to 5 percent for providers and facilities.

Therefore, the Departments do not anticipate that the proposed provisions in these proposed rules would have a significant effect on a substantial number of small entities. The Departments seek comment on this analysis.

In addition, section 1102(b) of the SSA requires the Departments to prepare a regulatory impact analysis if a rule under Title XVIII, Title XIX, or part B of Title 42 of the SSA may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to

⁶⁰ <https://www.sba.gov/document/support-table-size-standards>.

⁶¹ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

⁶² Adler, L., Hannick, K., and Lee, S. High Air Ambulance Charges Concentrated in Private Equity-Owned Carriers. USC-Brookings Schaeffer Initiative for Health Policy. October 13, 2020.

the provisions of section 603 of the RFA. For purposes of section 1102(b) of the SSA, the Departments define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the SSA, the Departments have determined that these proposed rules would only affect small rural hospitals if they are subject to an enforcement action. However, as discussed earlier in the RIA, a facility subject to investigation would incur a cost of approximately \$354. Therefore, the Departments are of the view that these proposed rules would not have a significant impact on the operations of a substantial number of small rural hospitals. The Departments seek comment on this analysis.

F. Unfunded Mandates

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 proposed 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. Currently, that threshold is approximately \$158 million. As discussed earlier in the RIA, plans, issuers, providers, and facilities, including providers of air ambulance services, would incur costs to comply with the proposed provisions of these proposed rules. The Departments estimate the combined impact on state, local, or Tribal governments and the private sector would not be above the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that Federal agencies must meet when they issue proposed rules that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has 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, and consulting with state insurance officials on an individual basis.

While developing this rule, the Departments attempted to balance the

states' interests in regulating health insurance issuers, providers, including providers of air ambulance services, and facilities with the need to ensure market stability. By doing so, the Departments complied with the requirements of Executive Order 13132.

Section 2799B-4(a)(1) of the PHS Act provides that states serve as the primary enforcement authority for these new requirements.⁶³ Section 2799B-4(a)(2) of the PHS Act provides that if the Secretary of HHS determines that a state has failed to substantially enforce any of these new requirements, then HHS shall assume enforcement of such provision. Therefore, the proposed amendments in this rulemaking would apply the process outlined in 45 CFR 150.201 through 150.221. by which HHS determines that a state is not substantially enforcing a PHS Act provision to the enforcement of the requirements in section 2799B-4. The remaining subparts of 45 CFR part 150 that relate to CMS enforcement of section 2799B-4 would apply only when the Secretary of HHS makes the determination that a state has substantially failed to enforce.

Section 2799B-4(c) of the PHS Act provides that "the sections specified in subsection (a)(1) shall not be construed to supersede any provision of state law which establishes, implements, or continues in effect any requirement or prohibition except to the extent that such requirement or prohibition prevents the application of a requirement or prohibition of such a section." These proposed rules would not preempt any state law except to the extent that the Secretary of HHS makes the determination that a state has substantially failed to enforce.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on August 26, 2021.

List of Subjects

5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Military personnel, Reporting and recordkeeping requirements, Retirement.

⁶³ 45 CFR 150.201 currently provides that ". . . each State enforces PHS Act requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State."

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

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 Part 144

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.

45 CFR Part 149

Balance billing, Health care, Health insurance, Reporting and recordkeeping requirements, Surprise Billing, State regulation of health insurance, Transparency in coverage.

45 CFR Part 150

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

Laurie Bodenheimer,

Associate Director, Healthcare and Insurance, Office of Personnel Management.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Ali Khawar,

Acting Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

OFFICE OF PERSONNEL MANAGEMENT

For the reasons stated in the preamble, the Office of Personnel Management proposes to amend 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.102 also issued under sections 11202(f), 11232(e), and 11246(b) of Pub. L. 105-33, 111 Stat. 251; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104-106, 110 Stat. 521 (36 U.S.C. 5522); Sec. 890.112 also issued under section 1 of Pub. L. 110-279, 122 Stat. 2604

(2 U.S.C. 2051); Sec. 890.113 also issued under section 1110 of Pub. L. 116–92, 133 Stat. 1198 (5 U.S.C. 8702 note); Sec. 890.301 also issued under section 311 of Pub. L. 111–3, 123 Stat. 64 (26 U.S.C. 9801); Sec. 890.302(b) also issued under section 1001 of Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029 (42 U.S.C. 300gg–14); Sec. 890.803 also issued under 50 U.S.C. 3516 (formerly 50 U.S.C. 403p) and 22 U.S.C. 4069c and 4069c–1; subpart L also issued under section 599C of Pub. L. 101–513, 104 Stat. 2064 (5 U.S.C. 5561 note), as amended; and subpart M also issued under section 721 of Pub. L. 105–261 (10 U.S.C. 1108), 112 Stat. 2061; 25 U.S.C. 1647b.

Subpart A—Administration and General Provisions

■ 2. Section 890.114 is amended by adding reserved paragraph (d) and paragraph (e) to read as follows:

§ 890.114 Surprise billing.

* * * * *

(e) A carrier must comply with requirements of 45 CFR 149.230 with respect to an FEHB plan in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage and within the time frame set forth in 45 CFR 149.230(a)(2). This paragraph (e) applies to data for each of the 2022 and 2023 calendar years.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 3.** The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ **Par. 4.** Section 54.9823–1 is added to read as follows:

§ 54.9823–1 Air ambulance reporting requirements.

(a) *In general.* Each group health plan that satisfies the requirements of 45 CFR 149.230 satisfies the requirements to submit a report to the Secretary of the Treasury pursuant to section 9823 of the Code.

(b) *Applicability.* This section applies to data for each of the 2022 and 2023 calendar years.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor proposes to amend 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–n, 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; Pub. L. 116–260 134 Stat. 1182; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 6. Section 2590.723 is added to read as follows:

§ 2590.723 Air ambulance reporting requirements.

(a) *In general.* Each group health plan or health insurance issuer offering group health insurance coverage that satisfies the requirements of 45 CFR 149.230 satisfies the requirements to submit a report to the Secretary of Labor pursuant to section 723 of the Employee Retirement Income Security Act of 1974, as amended.

(b) *Applicability.* This section applies to data for each of the 2022 and 2023 calendar years.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 144, 148, 149, and 150 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, 300gg–92, and 300gg–111 through 300gg–139, as amended.

■ 8. Section 144.101 is amended by revising paragraphs (e) introductory text and (e)(1) and (2) to read as follows:

§ 144.101 Basis and purpose.

* * * * *

(e) Part 150 of this subchapter implements the enforcement provisions of sections 2723, 2761, and 2799B–4 of the PHS Act, as well as section 106 of the No Surprises Act, with respect to the following:

(1) States that fail to substantially enforce one or more provisions of part 146 of this subchapter concerning group health insurance coverage, one or more provisions of part 147 of this subchapter concerning group or individual health insurance coverage, one or more provisions of part 148 of this subchapter concerning individual health insurance coverage or short-term, limited-duration insurance, or one or more provisions of part 149 of this subchapter concerning group or individual health insurance coverage, providers and facilities, and providers of air ambulance services.

(2) Issuers as defined in § 144.103, and providers and facilities, each as defined in § 150.103 of this subchapter, in States described in paragraph (e)(1) of this section.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 9. The authority citation for part 148 is revised to read as follows:

Authority: 42 U.S.C. 300gg–21 through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 10. Section 148.101 is revised to read as follows:

§ 148.101 Basis and purpose.

This part implements sections 2722 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to guarantee the renewability of all coverage in the individual market. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth and protects all individuals and family members who have, or seek, individual health insurance coverage from discrimination based on genetic information. It also sets forth reporting and disclosure requirements on health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance regarding the amount of direct and indirect compensation paid to agents or brokers associated with enrolling consumers in such coverage.

■ 11. Section 148.102 is amended by adding paragraph (a)(3) and revising paragraph (b) to read as follows:

§ 148.102 Scope and applicability date.

(a) * * *

(3) The requirements in § 148.410 that pertain to the disclosure and reporting of agent and broker compensation apply to health insurance issuers of individual health insurance coverage or short-term, limited-duration insurance, as defined in § 144.103 of this subchapter.

(b) *Applicability date.* Except as provided in § 148.124 (certificate of creditable coverage), § 148.170 (standards relating to benefits for mothers and newborns), § 148.180 (prohibition of health discrimination based on genetic information), and § 148.410 (reporting and disclosure of agent and broker compensation), 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, the definition of “short-term, limited-duration insurance” in § 144.103 of this subchapter is applicable October 2, 2018.

■ 12. Add subpart F to read as follows:

Subpart F—Requirements Related to Reporting and Disclosure

§ 148.410 Reporting and disclosure of agent and broker compensation for individual health insurance coverage or short-term, limited-duration insurance.

(a) *In general.* A health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance must make disclosures to individuals, as described in paragraph (c) of this section, and provide reports to the Secretary, as described in paragraph (d) of this section, regarding direct and indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage.

(b) *Definitions.* The following definitions apply to this section:

(1) *Agent or broker* has the meaning given in § 155.20 of this subchapter.

(2) *Commission schedule* means an itemized list or table that provides the commission levels that are paid by an issuer for the sale, placement, or renewal of individual health insurance coverage or short-term, limited-duration insurance.

(3) *Direct compensation* means monetary amounts, including sales and base commissions, paid by an issuer that are attributable directly to the policy, certificate, or contract of insurance and that are paid to an agent or broker for the sale, placement, or renewal of individual health insurance coverage or short-term, limited-duration insurance.

(4) *Indirect compensation* means payments by an issuer attributable

indirectly to a policy, certificate, or contract of insurance to agents, brokers, and other persons for items other than sales and base commissions (for example, service fees, consulting fees, finders’ fees, profitability and persistency bonuses, awards, prizes, volume-based incentives, and non-monetary forms of compensation).

(5) *Policyholder* means the individual who purchases individual health insurance coverage or short-term, limited-duration insurance and who is responsible for the payment of premiums.

(c) *Disclosure requirements—(1) General requirements.* An issuer described in paragraph (a) of this section must disclose to a potential or existing policyholder the amount of direct and indirect compensation provided to an agent or broker associated with enrolling the policyholder in individual health insurance coverage or short-term, limited-duration insurance.

(2) *Disclosures related to initial enrollments in a plan.* An issuer must disclose to all potential or new policyholders the amount of direct and indirect compensation, including the commission schedule applicable to the potential or current plan selection by all potential or new policyholders and an explanation of qualifying thresholds for the payment of indirect compensation to an agent or broker (or, if an issuer does not use commission schedules, the information described in paragraph (c)(5) of this section). Such disclosure must be made—

(i) Prior to when a potential policyholder finalizes their plan selection; and

(ii) On any documentation confirming the initial enrollment, including enrollment documentation required by applicable State or Federal law or an initial enrollment package.

(3) *Disclosures related to renewals of enrollment in a plan.* For renewals of enrollment in a plan, an issuer must disclose to a policyholder the amount of direct and indirect compensation, including, but not limited to, the commission schedule applicable to a plan renewal and an explanation of qualifying thresholds for the payment of indirect compensation to an agent or broker (or, if an issuer does not use commission schedules, the information described in paragraph (c)(5) of this section). Such disclosure must accompany the plan renewal notice required in § 147.106(f) of this subchapter or § 148.122(i), if applicable.

(4) *Default disclosure.* In the absence of any documentation required by State law or the requirement for a notice of

renewal of coverage, issuers must disclose the amount of direct and indirect compensation, including information typically itemized on a commission schedule used to determine agent or broker compensation as well as an explanation of qualifying thresholds for the payment of indirect compensation to an agent or broker, with the invoice for the first premium payment for the initial coverage term and for each renewal period.

(5) *Compensation information.* At a minimum, commission schedules or other documents that detail the applicable commission levels used to satisfy the requirements of this section must clearly specify commissions paid by the issuer to an agent or broker for the applicable plans for which the agent or broker has an appointment with the issuer, and distinguish between commission payments associated with new enrollments and such payments for renewed enrollments if the issuer differentiates compensation for those two types of enrollments. At a minimum, compensation information must also explain the qualifying thresholds for the payment of indirect compensation, such as bonuses, to an agent or broker. If an issuer of individual health insurance coverage or short-term, limited-duration insurance also offers direct or indirect compensation that is not captured by the commission schedule, the issuer must supplement the disclosure of the information on the commission schedule with additional documentation disclosing such other compensation.

(d) *Reporting requirements—(1) In general.* An issuer described in paragraph (a) of this section must report to the Secretary, in a form and manner prescribed by the Secretary, any direct and indirect compensation provided to an agent or broker associated with enrolling individuals in individual health insurance coverage and short-term, limited-duration insurance sold by the issuer.

(2) *Payments to intermediaries.* Reporting must reflect both compensation arrangements directly between the writing agent or broker and the issuer and compensation arrangements from the issuer to the writing agent or broker made through one or more intermediary organizations, for example, general line agencies or marketing organizations.

(3) *Reporting period.* The issuer must report, annually, on direct and indirect compensation paid to agents and brokers for individual health insurance coverage and short-term, limited-

duration insurance effective during the preceding calendar year.

(4) *Reporting deadline.* The report required under this paragraph (d) for a specific calendar year must be submitted to HHS no later than the last business day of July of the calendar year following the applicable reporting period.

(e) *Applicability.* The requirements of this section apply with respect to contracts executed on or after December 27, 2021, between an agent or broker and a health insurance issuer offering individual health insurance coverage or short-term, limited-duration insurance, as applicable. For the purpose of determining the date of contract execution, the execution of contractual addenda or revisions to the material terms of a pre-existing contract is deemed the execution of a new contract.

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

■ 13. The authority citation for part 149 continues to read as follows:

Authority: 42 U.S.C. 300gg–111 through 300gg–139, as amended.

■ 14. Section 149.10 is amended by revising paragraph (a) to read as follows:

§ 149.10 Basis and scope.

(a) *Basis.* This part implements Parts D and E of Title XXVII of the PHS Act, as well as section 106(a) of the No Surprises Act (Pub. L. 116–260, 134 Stat. 2852).

* * * * *

■ 15. Section 149.20 is amended by revising paragraph (a)(1) to read as follows:

§ 149.20 Applicability.

(a) * * *

(1) The requirements in subparts B, C, and D of this part apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter), except as specified in paragraph (b) of this section.

* * * * *

■ 16. Section 149.30 is amended by adding the definitions of “Air ambulance base” and “National Provider Identifier (NPI)” in alphabetical order to read as follows:

§ 149.30 Definitions.

* * * * *

Air ambulance base means a site from which a provider of air ambulance services operates to provide air ambulance services.

* * * * *

National Provider Identifier (NPI) has the meaning given in 45 CFR 162.406.

* * * * *

■ 17. Add subpart C to read as follows:

Subpart C—Transparency and Reporting Requirements for the Group and Individual Health Insurance Markets

Sec.

149.210—149.220 [Reserved]

149.230 Reporting requirements regarding air ambulance services for plans and issuers.

§§ 149.210–149.220 [Reserved]

§ 149.230 Reporting requirements regarding air ambulance services for plans and issuers.

(a) *Reporting requirements*—(1) *General requirements.* A group health plan or health insurance issuer offering group or individual health insurance coverage must submit to the Secretary a report that includes the information described in paragraph (b) of this section for calendar years 2022 and 2023.

(2) *Timing and form of report.* The reports reflecting the data for each of the 2022 and 2023 calendar year reporting periods must be submitted to the Secretary by March 31, 2023, and by March 30, 2024, respectively, in the form and manner prescribed by the Secretary in guidance. The report must include data relevant to services furnished within the reporting period as well as data relevant to services for which payments were made within the reporting period.

(3) *Transfer of business.* A health insurance issuer offering group or individual health insurance coverage that acquires a line or block of business from another issuer offering group or individual health insurance coverage must submit the information required in paragraph (b) of this section on behalf of the acquired business, for the entire calendar year during which the acquisition took place. The reporting requirement in this paragraph (a)(3) also applies to the selling and acquiring issuers if a sale or transfer occurs as a result of issuers being merged, combined, spun off, affected by, or engaging in any similar transaction during a calendar year. To ensure completeness and timeliness of reporting of all relevant air ambulance services data, the Secretary may provide in guidance additional examples of what constitutes a transfer or acquisition for purposes of this paragraph (a)(3).

(b) *Required data elements.* The report required in paragraph (a) of this

section must include the following data elements with respect to air ambulance services provided under a group health plan or group or individual health insurance coverage to participants, beneficiaries, or enrollees during the relevant reporting period, for each claim for air ambulance services that was received or paid for during the reporting period:

(1) Identifying information for any group health plan, plan sponsor, or issuer, and any entity reporting on behalf of the plan or issuer, as applicable.

(2) Market type for the plan or coverage (individual, large group, small group, self-insured plans offered by small employers, self-insured plans offered by large employers, and Federal Employees Health Benefits).

(3) Date of service.

(4) Billing NPI information.

(5) Current Procedural Terminology (CPT) code or Healthcare Common Procedure Coding System (HCPCS) code information.

(6) Transport information (including aircraft type, loaded miles, pick-up (origin zip code) and drop-off (destination zip code) locations, whether the transport was emergent or non-emergent, whether the transport was an inter-facility transport, and, to the extent this information is available to the plan or issuer, the service delivery model of the provider (such as government-sponsored (Federal, State, county, city/township, other municipal), public-private partnership, tribally-operated program in Alaska, hospital-owned or sponsored program, hospital independent partnership (hybrid) program, independent).

(7) Whether the provider had a contract with the group health plan or issuer of group or individual health insurance coverage, as applicable, to furnish air ambulance services under the plan or coverage, respectively.

(8) Claim adjudication information, including whether the claim was paid, denied, appealed; denial reason; and appeal outcome.

(9) Claim payment information, including submitted charges, amounts paid by each payor, and cost sharing amount, if applicable.

(c) *Special rules to prevent unnecessary duplication*—(1) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of paragraph (a) of this section if the plan requires the health insurance issuer offering the coverage to report the information required by this section pursuant to a written agreement.

Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to report the information required under paragraph (a) of this section in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the reporting requirements of paragraph (a) of this section.

(2) *Other contractual arrangements.* A group health plan or issuer of group or individual health insurance coverage may satisfy the requirements under paragraph (a) of this section by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) reports the information required in paragraph (a) of this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in accordance with this section, the plan or issuer violates the reporting requirements of paragraph (a) of this section.

■ 18. Section 149.460 is added to read as follows:

§ 149.460 Reporting requirements regarding air ambulance services for providers of air ambulance services.

(a) *Reporting requirements*—(1) *General requirements.* A provider of air ambulance services must submit to the Secretary a report which includes the information described in paragraph (b) of this section for calendar years 2022 and 2023.

(2) *Timing and form of report.* The reports reflecting the data for each of the 2022 and 2023 calendar year reporting periods must be submitted to the Secretary by March 31, 2023, and by March 30, 2024, respectively, in the form and manner prescribed by the Secretary in guidance. The report must include data relevant to services furnished within the reporting period as well as data relevant to services for which payments were made within the reporting period.

(3) *Transfer of business.* A provider of air ambulance services that acquires a line or block of business from another provider of air ambulance services must submit the information required in paragraph (b) of this section on behalf of the acquired business, for the entire calendar year during which the acquisition took place. The reporting requirement in this paragraph (a)(3) also applies to the selling and acquiring providers of air ambulance services if a sale or transfer occurs as a result of

providers of air ambulance services being merged, combined, spun off, affected by, or engaging in any similar transaction during a calendar year. To ensure completeness and timeliness of reporting of all relevant air ambulance services data, the Secretary may provide in guidance additional examples of what constitutes a transfer or acquisition for purposes of this paragraph (a)(3).

(b) *Required data elements.* The report required in paragraph (a) of this section must include the following data:

(1) *Corporate information.* Each provider of air ambulance services must report the following information about their company or organization:

(i) Identifying information for the company or organization.

(ii) Identifying information for the parent organization, owner, other proprietor, or sponsor of the provider of air ambulance services.

(iii) Information on all air ambulance bases owned, leased, operated, or used by the provider of air ambulance services.

(iv) NPIs registered to the provider of air ambulance services.

(2) *Air ambulance base information.* The following information must be reported separately for each air ambulance base owned, leased, or operated by the provider of air ambulance services:

(i) Location (City and State of the air ambulance base).

(ii) NPIs associated with the base.

(iii) Number, type, and other characteristics of the aircraft located on the base;

(iv) The number and type of staff.

(v) The number and type of air ambulance responses and transports per aircraft.

(vi) Total air ambulance responses per base and total air ambulance responses that did not result in transports.

(vii) Information regarding any contracts the provider has with group health plans or health insurance issuers to furnish air ambulance services associated with the base.

(viii) Air medical subscriptions or ambulance/emergency medical service membership programs associated with the base.

(ix) Non-direct payor contracts (such as waiver, rental, lease, or supplemental arrangements) with group health plans, health insurance issuers, or other entities, such as third-party administrators or provider networks, associated with the base.

(x) Service delivery model(s) (such as government-sponsored (Federal, State, county, city/township, other municipal), public-private partnership,

tribally-operated program in Alaska, hospital-owned or sponsored program, hospital independent partnership (hybrid) program, independent), and whether the base shares operational costs with affiliated or sponsor organizations (such as a hospital or municipality), if applicable.

(xi) Whether the base operates ground ambulance services as well as air ambulance services.

(3) *Cost information.* The following information must be reported separately for each air ambulance base described in paragraph (b)(2) of this section, as well as at the regional or corporate level, if applicable:

(i) Labor costs.

(ii) Facility costs.

(iii) Vehicle costs.

(iv) Equipment and supplies costs.

(v) Vendor costs.

(vi) Overhead costs (including administrative and general expenses, insurance costs, and training costs).

(4) *Revenue information.* The following information must be reported separately for each air ambulance base described in paragraph (b)(2) of this section, as well as at the regional or corporate level, if applicable:

(i) Revenue from paid air ambulance transports, by payor type (including Medicare fee-for-service (FFS), Medicare Advantage, Medicaid, Veterans' Health Administration, TRICARE, Indian Health Service, group health plan, health insurance issuer, Federal Employees Health Benefits plan, Worker's Compensation, patient cost sharing, or patient self-pay).

(ii) Revenue from other sources including, but not limited to: Contracts with facilities such as hospitals, prisons, and nursing homes; revenue from emergency air medical services other than for transports (such as transportation of medical personnel or equipment); revenue from sub-contracted ambulance services; fees for standby events; payments from non-direct contracts such as waiver, rental, lease, and supplemental arrangements; air medical subscriptions and ambulance or emergency medical service membership programs; charitable donations and foundation funding; program-related investments; receipt of local taxes earmarked for emergency medical services; contract revenues from local governments in return for air ambulance services; enterprise funds and utility rates; sales of assets and services; bond or debt financing; State or local donation of vehicles or durable equipment; or funding grants or the provision of time-limited funding from a government

(including Federal, State, local, or other)).

(5) *Transport information.* The following information must be reported separately for each air ambulance transport provided during the reporting period:

(i) Date of service.
 (ii) Billing NPI information.
 (iii) Current Procedural Terminology (CPT) code or Healthcare Common Procedure Coding System (HCPCS) code information.

(iv) Air ambulance base.
 (v) Loaded miles.
 (vi) Pick-up (origin zip code) and drop-off (destination zip code) locations.

(vii) Duration of flight.
 (viii) Whether the transport was emergent or non-emergent.

(ix) Whether the transport was a scene response, inter-facility, or other transport;

(x) Primary payor information, including payor type (such as Medicare FFS, Medicare Advantage, Medicaid, Veterans' Health Administration, TRICARE, Indian Health Service, group health plan, health insurance issuer, Federal Employees Health Benefits plan, Workers' Compensation, patient cost-sharing, or patient self-pay).

(xi) Information regarding any contracts the provider has with the group health plan or health insurance issuer, if and as applicable, to provide air ambulance services under the plan or coverage, respectively.

(xii) Payment methodology (such as base rate, mileage, and intervention or other charges), if applicable.

(xiii) Claim adjudication information, including whether the claim was paid, denied, appealed, denial reason, and appeal outcome, if applicable.

(xiv) Claim/transport payment information, including submitted charges, amount paid by payor other than patient, cost-sharing amount (if applicable), amount billed to patient, amount collected from patient, whether the bill was referred to collections, and payments from sources other than the primary payor.

PART 150—CMS ENFORCEMENT OF GROUP AND INDIVIDUAL INSURANCE MARKET, AND PROVIDER AND FACILITY REQUIREMENTS

■ 19. The authority citation for part 150 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92, 300gg-118, and 300gg-134, as amended.

■ 20. The heading for part 150 is revised to read as set forth above.

■ 21. Section 150.101 is amended by revising paragraphs (a) and (b)(2) and

adding paragraph (b)(3) to read as follows:

§ 150.101 Basis and scope.

(a) *Basis.* This part implements CMS's enforcement authority under sections 2723, 2761, and 2799B-4 of the PHS Act, as well as section 106(e) of the No Surprises Act (Pub. L. 116-260, 134 Stat. 2852).

(b) * * *

(2) *Enforcement with respect to health insurance issuers.* The States have primary enforcement authority with respect to the requirements of Title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If CMS determines under subpart B of this part that a State is not substantially enforcing Title XXVII of the PHS Act, including the implementing regulations in parts 146, 147, 148, and 149 of this subchapter, CMS enforces them under subpart C of this part.

(3) *Enforcement with respect to providers and facilities.* The States have primary enforcement authority with respect to the requirements of Part E of Title XXVII of the PHS Act that apply to providers and facilities. If CMS determines under subpart B of this part that a State is not substantially enforcing Part E of Title XXVII of the PHS Act, and its implementing regulations in part 149 of this subchapter, CMS enforces them under subpart E of this part. CMS has primary enforcement authority with respect to the provisions of section 106(a) of the No Surprises Act, including the implementing regulations in part 149 of this subchapter, which CMS enforces under subpart E of this part.

■ 22. Section 150.103 is amended by—

- a. Revising the introductory text;
- b. Adding the definition of "Facility" in alphabetical order;
- c. In the definition of "Individual health insurance policy or individual policy," revising the introductory text and paragraph (2);
- d. Revising the definition of "PHS Act requirements;" and
- e. Adding the definitions "Provider" in alphabetical order.

The revisions and additions read as follows:

§ 150.103 Definitions.

The definitions that appear in parts 144 and 149 of this subchapter apply to this part unless stated otherwise. As used in this part:

* * * * *

Facility means a health care facility, an emergency department of a hospital, and an independent freestanding

emergency department, as those terms are defined in § 149.30 of this subchapter, and any other facility subject to the requirements in Part E of Title XXVII of the PHS Act.

* * * * *

Individual health insurance policy or individual policy means the legal document or contract issued by an issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in § 144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual health insurance coverage subject to the requirements of parts 147, 148, and 149 of this subchapter. The term "individual health insurance policy" includes a policy that is—

* * * * *

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of parts 146, 147, and 149 of this subchapter.

PHS Act requirements means the requirements of Title XXVII of the PHS Act and its implementing regulations in parts 146, 147, 148, and 149 of this subchapter.

* * * * *

Provider means a physician or other health care provider as defined in § 149.30 of this subchapter, and a provider of air ambulance services as defined in § 149.30 of this subchapter.

* * * * *

■ 23. Revise the heading for subpart B to read as follows:

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing to Substantially Enforce PHS Act Requirements

■ 24. Section 150.201 is revised to read as follows:

§ 150.201 State enforcement.

Except as provided in subparts C and E of this part, each State enforces PHS Act requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State and with respect to providers and facilities that furnish items or services to individuals in the State.

■ 25. Section 150.203 is amended by revising the introductory text to read as follows:

§ 150.203 Circumstances requiring CMS enforcement.

CMS enforces PHS Act requirements to the extent warranted (as determined

by CMS) in any of the following circumstances:

* * * * *

■ 26. Section 150.205 is amended by revising paragraphs (d) and (e)(2) to read as follows:

§ 150.205 Sources of information triggering an investigation of State enforcement.

* * * * *

(d) Information from the governors; commissioners of insurance, or chief insurance regulatory officials, or officials responsible for regulating health maintenance organizations (HMOs) of the various States; and directors of public health or any other State department, agency, or board of the various States with applicable oversight authority regarding the status of their enforcement of PHS Act requirements.

(e) * * *

(2) Not pre-empted as provided in § 146.143 (relating to group market provisions) and § 148.210 (relating to individual market requirements) on the basis that they prevent the application of a PHS Act requirement.

* * * * *

■ 27. Section 150.211 is amended by revising paragraph (b) and adding paragraph (d) to read as follows:

§ 150.211 Notice to the State.

* * * * *

(b) If the alleged failure involves a health insurance issuer, the insurance commissioner or chief insurance regulatory official.

* * * * *

(d) If the alleged failure involves a provider or facility, the official responsible for regulating such provider or facility, if different from the officials listed in paragraphs (b) and (c) of this section.

■ 28. Section 150.221 is amended by revising paragraphs (a)(2) and (b) to read as follows:

§ 150.221 Transition to State enforcement.

(a) * * *

(2) Instructions to issuers, providers, and facilities, as applicable.

* * * * *

(b) CMS may also negotiate a process to ensure that, to the extent practicable, as permitted by law, and as applicable, its records documenting issuer, provider, and facility compliance and other relevant areas of CMS's enforcement operations are made available to the State regulatory authority that will assume enforcement responsibility.

■ 29. Section 150.303 is amended by revising the section heading and

paragraphs (a) introductory text, (a)(2), and (c) to read as follows:

§ 150.303 Basis for initiating an investigation or examination.

(a) *Information.* Any information that indicates that any issuer may be failing to meet the PHS Act requirements or that any group health plan that is a non-Federal governmental plan may be failing to meet an applicable PHS Act requirement, may warrant an investigation or market conduct examination at CMS's discretion. An investigation or examination may include a review of any information CMS identifies as relevant to determine if a violation of the PHS Act has occurred. CMS may consider, but is not limited to considering, the following sources or types of information to determine if an investigation or market conduct examination is warranted:

* * *

(2) Reports from providers and facilities, State insurance departments, the National Association of Insurance Commissioners, and other Federal and State agencies.

* * *

(c) *Random and targeted investigations and market conduct examinations.* CMS may conduct random or targeted investigations or market conduct examinations to ensure that health insurance issuers offering health insurance coverage in the individual or group markets, and non-Federal governmental plans, are in compliance with applicable PHS Act requirements.

■ 30. Section 150.307 is amended by revising the introductory text and paragraphs (a) and (b) and adding paragraph (d) to read as follows:

§ 150.307 Notice to responsible entities.

If information received under § 150.303(a) indicates a potential violation, or if CMS selects an issuer or non-Federal governmental plan for investigation under § 150.303(c), CMS provides written notice to the responsible entity or entities identified under § 150.305. The notice does the following:

(a) Describes the information received under § 150.303(a) that gave rise to the investigation, or notifies the responsible entity that it was selected by CMS for investigation under § 150.303(c) and identifies the PHS Act requirements that are the focus of the investigation, as applicable.

(b) Provides the date by which the responsible entity or entities must respond and provide any documentation CMS identifies as relevant for purposes of an

investigation, and by which the responsible entity or entities can provide additional information, including documentation of compliance as described in § 150.311, that, in the responsible entity's view, will aid CMS in evaluating the entity's compliance with the PHS Act requirements identified in the notice.

* * * * *

(d) States that CMS may require a plan of corrective action.

■ 31. Section 150.309 is revised to read as follows:

§ 150.309 Request for extension.

In circumstances in which an entity cannot prepare a response to CMS or provide the requested information by the deadline provided in the notice under § 150.307, the entity may submit a written request for an extension from CMS detailing the reason for the extension request and showing good cause. Examples of what CMS would consider good cause include, but are not limited to, when a responsible entity indicates it has limited staffing resources to prepare a response, or when a responsible entity requests clarification from CMS regarding its request for information. If CMS grants the extension, the responsible entity must respond to the notice within the time frame specified in CMS's letter granting the extension of time. Failure to respond within the initial deadline provided in the notice, or within any extended time frame, may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a violation of PHS Act requirements.

■ 32. Section 150.311 is amended by revising paragraph (e) to read as follows:

§ 150.311 Responses to allegations of noncompliance.

* * * * *

(e) Documentation of the entity's issuance of conforming policies, certificates of insurance, plan documents, or amendments to policyholders or certificate holders before the issuance of the notice to the responsible entity or entities described in § 150.307 or § 150.313(e).

* * * * *

■ 33. Section 150.313 is amended by revising paragraphs (b), (c), and (e) and adding paragraphs (f), (g), (h), and (i) to read as follows:

§ 150.313 Market conduct examinations.

* * * * *

(b) *General.* If, based on the information described in § 150.303(a), CMS finds evidence that a responsible entity may be in violation of a PHS Act

requirement, or if CMS randomly selects an issuer or non-Federal governmental plan for examination under § 150.303(c), CMS may initiate a market conduct examination to ensure the entity is in compliance with applicable PHS Act requirements. CMS may conduct the examination either at the site of the issuer or other responsible entity, or a site CMS selects.

(c) *Appointment of examiners.* When CMS identifies an issue that warrants further review or randomly selects an issuer or non-Federal governmental plan for examination, CMS will appoint one or more examiners to perform the examination and instruct them as to the scope of the examination.

* * * * *

(e) *Initiation of examination.* CMS initiates an examination by providing written notice to the responsible entity. The notice does the following:

(1) Describes the information received under § 150.303(a) that served as the basis for CMS's determination that a market conduct examination is warranted, or notifies the responsible entity that it was selected by CMS for examination under § 150.303(c), as applicable;

(2) Describes the scope of the examination;

(3) Identifies the examiners;

(4) States that a civil money penalty may be assessed; and

(5) States that CMS may require a plan of corrective action.

(f) *Documentation requests; extension of time.* The responsible entity must forward to the site of examination any documentation CMS identifies as relevant for purposes of the examination. CMS will provide the responsible entity with an opportunity to provide additional information, including documentation of compliance as described in § 150.311, that the responsible entity believes will aid CMS in conducting the examination. This initial request will provide the responsible entity the date by which to forward the specified documentation to the location that CMS identifies. In circumstances in which an entity cannot prepare a response and provide the requested information to CMS by the deadline provided in the initial request, the entity may make a written request for an extension from CMS detailing the reason for the extension request and showing good cause. Examples of what CMS would consider good cause include, but are not limited to, when a responsible entity indicates it has limited staffing resources to prepare a response, or when a responsible entity requests clarification from CMS

regarding its request for information. If CMS grants the extension, the responsible entity must respond to the documentation request within the time frame specified in CMS's letter granting the extension request. Failure to respond by the deadline provided in the initial request, or within the extended time frame, may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a potential violation of applicable PHS Act requirements.

(g) *Field work.* CMS will review the documentation submitted under paragraph (f) of this section. During the course of the examination, CMS may request additional information or documentation and will specify in the request the time frame allotted for providing it. In circumstances in which an entity cannot prepare a response and provide the requested information to CMS within the allotted time frame, the entity may submit to CMS a written request for an extension from CMS detailing the reason for the extension request and showing good cause. Examples of what CMS would consider good cause include, but are not limited to, when a responsible entity indicates it has limited staffing resources to prepare a response, or when a responsible entity requests clarification from CMS regarding its request for information. If CMS grants the extension, the responsible entity must respond to the documentation request within the time frame specified in CMS's letter granting the extension request. Failure to respond and provide such additional documentation to CMS within the allotted time frame, or within an extended time frame as granted by CMS, may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a potential violation of applicable PHS Act requirements. During the course of the examination, upon review of the documentation submitted, CMS may identify and notify the responsible entity of any potential PHS Act violations and provide the responsible entity an opportunity to respond with additional information, including documentation of compliance as described in § 150.311, that the responsible entity believes demonstrates compliance or will otherwise aid CMS in conducting the examination.

(h) *Draft report of market conduct examination—(1) Contents of report.* CMS will, upon completion of the examination, provide to the responsible entity a draft examination report that will include the scope of the examination, any findings of a PHS Act

violation, and any proposed actions the responsible entity would need to take to correct such violation.

(2) *Response from the responsible entity.* With respect to each examination issue identified in the draft examination report, the responsible entity may:

(i) Concur, in whole or in part, with CMS's position(s) as outlined in the draft examination report, explaining any corrective actions that have been or will be implemented; or

(ii) Dispute, in whole or in part, CMS's position(s), clearly outlining the basis for its dispute and submitting illustrative examples where appropriate.

(i) *Final report of market conduct examination.* Upon receipt of a response from the responsible entity under paragraph (h)(2) of this section, CMS will provide to the responsible entity a final examination report containing CMS's findings relevant to each examination issue that will consist of one or more of the following:

(1) CMS's concurrence with the responsible entity's position;

(2) CMS's disagreement with the responsible entity's position;

(3) CMS's determination that any corrective actions implemented by the responsible entity sufficiently addressed the identified PHS Act violation;

(4) CMS's determination that the corrective actions implemented by the responsible entity have not sufficiently addressed the identified PHS Act violation, and information on any further corrective actions deemed necessary by CMS; or

(5) Notice to the responsible entity that has disagreed with a CMS finding and that has not undertaken corrective actions that there exists a violation of applicable PHS Act requirements and any actions the responsible entity must take prospectively to correct such violation.

■ 34. Section 150.319 is amended by revising paragraph (a)(1) to read as follows:

§ 150.319 Determining the amount of the penalty—mitigating circumstances.

* * * * *

(a) * * *

(1) Before receipt of the notice issued under § 150.307 or § 150.313(e), implemented and followed a compliance plan as described in § 150.311(f).

* * * * *

■ 35. Section 150.321 is amended by adding paragraph (d) to read as follows:

§ 150.321 Determining the amount of penalty—aggravating circumstances.

* * * * *

(d) The entity fails to cooperate with a CMS investigation or market conduct examination.

■ 36. Section 150.325 is revised to read as follows:

§ 150.325 Settlement authority.

Nothing in §§ 150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with § 150.307 or § 150.313(e), or to compromise on any penalty provided for in §§ 150.315 through 150.323.

■ 37. Section § 150.401 is amended by revising the definition of “Respondent” to read as follows:

§ 150.401 Definitions.

* * * * *

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to § 150.343 or § 150.515.

■ 38. Section 150.405 is amended by revising paragraph (a) to read as follows:

§ 150.405 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with § 150.407(a), within 30 days after the date of issuance of either CMS’s notice of proposed determination under § 150.343 or § 150.515, or notice that an alternative dispute resolution process has terminated. The request for hearing must be addressed as instructed in the notice of proposed determination. “Date of issuance” is five (5) days after the filing date, unless there is a showing that the document was received earlier.

* * * * *

■ 39. Section 150.417 is amended by revising paragraph (b)(1) to read as follows:

§ 150.417 Issues to be heard and decided by ALJ.

* * * * *

(b) * * *

(1) Applies the factors that are identified in § 150.317 or § 150.513.

* * * * *

■ 40. Section 150.445 is amended by revising paragraphs (g), (h), and (j) to read as follows:

§ 150.445 Evidence.

* * * * *

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under § 150.317, § 150.323, or § 150.513 to consider the entity’s prior record of compliance, to show motive, opportunity, intent, knowledge,

preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether CMS’s notice sent in accordance with § 150.307, § 150.313(e), § 150.343, § 150.505, or § 150.515 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence, and to cross-examine witnesses.

* * * * *

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after CMS’s notice under § 150.307, § 150.313(e), or § 150.505.

■ 41. Section 150.455 is amended by adding paragraph (b)(9) to read as follows:

§ 150.455 Sanctions.

* * * * *

(b) * * *

(9) In the case of a violation of part 149 of this subchapter, ordering the party or attorney to pay attorneys’ fees and other costs caused by the failure or misconduct.

■ 42. Add subpart E to read as follows:

Subpart E—CMS Enforcement with Respect to Providers and Facilities

Sec.

- 150.501 General rule regarding the imposition of civil money penalties.
150.503 Basis for initiating an investigation; injunctive relief.
150.505 Notice to providers or facilities.
150.507 Request for extension.
150.509 Responses to allegations of noncompliance.
150.511 Liability for penalties.
150.513 Amount of penalty.
150.515 Notice of proposed determination.
150.517 Hearing.
150.519 Failure to request a hearing.
150.521 Collateral estoppel.
150.523 Judicial review.
150.525 Notice to other agencies.

Subpart E—CMS Enforcement with Respect to Providers and Facilities

§ 150.501 General rule regarding the imposition of civil money penalties.

(a) If any provider or facility that is subject to CMS’s enforcement authority under § 150.101(b)(3) fails to comply with a requirement in Title XXVII, Part E of the PHS Act, such provider or facility may be subject to a civil money penalty as described in this subpart.

(b) If any provider of air ambulance services fails to timely submit the information required in section 106(a) of

the No Surprises Act, such provider may be subject to a civil money penalty as described in this subpart.

§ 150.503 Basis for initiating an investigation; injunctive relief.

(a) Basis for investigation. Any information that indicates that any provider or facility may be failing to meet the PHS Act requirements or submit the information required in section 106(a) of the No Surprises Act may warrant an investigation at CMS’s discretion. An investigation may include a review of any information CMS identifies as relevant to determine if a violation of the PHS Act or section 106(a) of the No Surprises Act has occurred. CMS may consider, but is not limited to considering, the following sources or types of information to determine if an investigation is warranted:

- (1) Complaints.
(2) Reports from plans or issuers, State insurance departments, State health departments, medical boards, the National Association of Insurance Commissioners, and any other Federal or State agencies.

(3) Any other information that indicates potential noncompliance with PHS Act requirements or section 106(a) of the No Surprises Act.

(b) Who may file a complaint. Any aggrieved entity or individual, or any entity or personal representative acting on that individual or entity’s behalf, may file a complaint with CMS if he or she believes that a right to which the aggrieved individual or entity is entitled under PHS Act requirements is being, or has been, denied or abridged as a result of any action or failure to act on the part of a provider or facility.

(c) Random and targeted investigations. CMS may conduct random or targeted investigations to ensure that providers and facilities are in compliance with applicable PHS Act requirements and section 106(a) of the No Surprises Act.

(d) Injunctive relief. Whenever CMS has reason to believe that any provider or facility has engaged, is engaging, or is about to engage in any activity which makes such provider or facility subject to a civil money penalty under this subpart, CMS may bring an action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the provider or facility from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil money penalty if any such penalty were to be imposed or to seek other appropriate relief.

§ 150.505 Notice to providers or facilities.

If CMS receives information under § 150.503(a) that indicates a potential violation of the PHS Act or section 106(a) of the No Surprises Act, or if CMS selects a provider or facility for investigation under § 150.503(c), CMS provides written notice to the provider or facility. The notice does the following:

(a) Describes the information received under § 150.503(a) that gives rise to the potential violation, notifies the provider or facility that it was selected by CMS for investigation under § 150.503(c) and the PHS Act requirements that are the focus of the investigation, or describes the data that was required under section 106(a) of the No Surprises Act and the implementing regulations in part 149 of this subchapter but not submitted by a provider of air ambulance services, as applicable.

(b) Provides the date by which the provider or facility must respond and forward any documentation CMS identifies as relevant for purposes of an investigation, including overdue data regarding air ambulance services, and can provide additional information, including documentation of compliance as described in § 150.509 that, in the provider or facility's view, will aid CMS in evaluating the entity's compliance with the PHS Act or No Surprises Act requirements identified in the notice.

(c) States that a civil money penalty may be assessed should the entity be found to be out of compliance with applicable PHS Act requirements or section 106(a) of the No Surprises Act.

(d) States that CMS may require a plan of corrective action.

§ 150.507 Request for extension.

In circumstances in which a provider or facility cannot prepare a response to CMS or provide the requested information by the deadline provided in the notice under § 150.505, the provider or facility may make a written request for an extension from CMS detailing the reason for the extension request and showing good cause. Examples of what CMS would consider good cause include, but are not limited to, when a responsible entity indicates it has limited staffing resources to prepare a response, or when a responsible entity requests clarification from CMS regarding its request for information. If CMS grants the extension, the provider or facility must respond to the notice within the time frame specified in CMS's letter granting the extension of time. Failure to respond within the initial deadline provided in the notice, or within the extended time frame, may result in CMS's imposition of a civil

money penalty based upon the complaint or other information alleging or indicating a violation of PHS Act requirements or section 106(a) of the No Surprises Act.

§ 150.509 Responses to allegations of noncompliance.

In determining whether to impose a civil money penalty, CMS reviews and considers documentation provided in any complaint or other information, as well as any additional information provided by the provider or facility to demonstrate that it has complied with relevant requirements. The following are examples of documentation that a provider or facility may submit for CMS's consideration in determining whether a civil money penalty should be assessed and the amount of any civil money penalty:

(a) Any documentation indicating a provider or facility complied with the requirements in part 149 of this subchapter, including but not limited to claims, medical bills, notice and consent forms, disclosures, data related to air ambulance services, or any other documents if those documents form the basis of a complaint or allegation of noncompliance, or the basis for the provider or facility to refute the complaint or allegation.

(b) Any other evidence that refutes an allegation of noncompliance.

(c) Evidence that the provider or facility did not know, and exercising due diligence could not have known, of the violation, and, if applicable, that the provider or facility undertook a corrective action, such as withdrawing the bill that was in violation and reimbursing the health plan or participant, beneficiary, or enrollee for any payment received in response to the bill that was withdrawn.

(d) Evidence documenting the development and implementation of internal policies and procedures by a provider or facility to ensure compliance with PHS Act requirements and section 106(a) of the No Surprises Act, as applicable. Those policies and procedures may include or consist of a voluntary compliance program. Any such program must do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the provider or facility's commitment to the compliance process.

(2) Include the name of an individual responsible for compliance.

(3) Describe an effective monitoring process designed to identify practices that do not comply with PHS Act requirements and section 106(a) of the No Surprises Act, as applicable, and to

provide reasonable assurances that noncompliant practices are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(e) Evidence documenting the provider's or facility's record of previous compliance with PHS Act requirements and section 106(a) of the No Surprises Act, as applicable.

(f) Evidence documenting a provider of air ambulance services' good faith efforts to submit missing information that such providers are required to submit pursuant to § 149.460 of this chapter. This must include the submission and implementation of a corrective action plan that does the following:

(1) Identifies the cause underlying the submission of incomplete data and effectively articulates and demonstrates the measures that will be taken to submit complete data;

(2) Provides the timeline for submitting complete data;

(3) Provides the name of the individual in the organization responsible for overseeing the corrective actions and submitting complete data; and

(4) Addresses procedures to improve internal policies to ensure that incomplete data reports are identified and completed prior to submission for future reporting periods.

§ 150.511 Liability for penalties.

(a) No action under this part will be entertained unless commenced within 6 years from the date when the claim was presented, the request for payment was made, or the violation occurred.

(b) Under this part, a principal is liable for penalties for the actions of his or her agent acting within the scope of his or her agency. This paragraph (b) does not limit the underlying liability of the agent.

§ 150.513 Amount of penalty.

(a) *Maximum amount.* (1) If a provider or facility is found to be in violation of a PHS Act requirement, CMS may impose a civil money penalty in an amount not to exceed \$10,000 per violation, adjusted annually under 45 CFR part 102. Penalties imposed under this part are in addition to any other penalties prescribed or allowed by law.

(2) If a provider of air ambulance services is found to be in violation of section 106(a) of the No Surprises Act, CMS may impose a civil money penalty in an amount not to exceed \$10,000 per year of violation, adjusted annually under 45 CFR part 102. Penalties imposed under this part are in addition

to any other penalties prescribed or allowed by law.

(b) *Factors.* Except as otherwise provided in this part, in determining the amount of any penalty in accordance with this part, CMS will consider the following factors—

(1) The nature of violations and circumstances under which they were presented.

(2) The degree of culpability of the provider or facility against which a civil money penalty is proposed.

(3) The provider or facility's history of prior violations, including whether at any time before determination of the current violation or violations, CMS or any State found the provider or facility liable for civil or administrative sanctions in connection with a violation of PHS Act requirements or section 106(a) of the No Surprises Act, as applicable.

(4) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(5) The level of financial and other impacts on affected individuals.

(6) Such other matters as justice may require.

(c) *Mitigating circumstances.* For every violation subject to a civil money penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted in paragraph (a) of this section to reflect that fact. As guidelines for taking into account the factors listed in paragraph (b) of this section, CMS considers the following as mitigating circumstances:

(1) Before receipt of the notice issued under § 150.505, the provider or facility implemented and followed a compliance plan as described in § 150.509.

(2) There were no previous complaints of noncompliance against the provider or facility.

(3) In the case of a provider or facility responsible for an erroneous bill, the provider or facility made adjustments to business practices to come into compliance with PHS Act requirements, so that the following occur:

(i) The provider or facility identified all participants, beneficiaries and enrollees who are or were wrongly billed.

(ii) The provider or facility withdrew the bill or reimbursed the affected individuals who were wrongly billed so that, to the extent practicable, the affected individuals are in the same position that they would have been in had the violation not occurred.

(iii) The provider or facility completed the adjustments to business practices in a timely manner.

(4) The provider or facility demonstrated that the violation is an isolated occurrence.

(d) *Aggravating circumstances.* For every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS sets the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by this section to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(1) The frequency of violation indicates a pattern of widespread occurrence.

(2) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(3) The provider or facility does not provide documentation showing that substantially all of the violations were corrected.

(e) *Waiver of the penalty.* CMS shall waive a civil money penalty if:

(1) The provider or facility does not knowingly violate, and exercising due diligence should not have reasonably known it violated, part 149 of this subchapter with respect to a participant, beneficiary, or enrollee, and such provider or facility withdraws the bill that was in violation of such provision and reimburses the group health plan, health insurance issuer, or affected individual, as applicable, in an amount equal to the difference between the amount billed and the amount allowed to be billed, plus interest at the rate established annually by the Secretary of the Treasury pursuant to 31 U.S.C. 3717, within 30 days of the violation; or

(2) In the case of a provider of air ambulance services that submits only part of the information required in § 149.460 of this subchapter, if the provider demonstrates a good faith effort in working with the Secretary to submit any missing information.

(f) *Settlement authority.* Nothing in this section limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with § 150.505 or to compromise on any penalty provided for in § 150.515.

(g) *Hardship exemption.* The Secretary may establish a hardship exemption to the penalties under this subpart.

§ 150.515 Notice of proposed determination.

(a) If CMS proposes a penalty, in accordance with this subpart, CMS will serve on the provider or facility, in any manner authorized by Rule 4 of the

Federal Rules of Civil Procedure, written notice of CMS's intent to impose a penalty. The notice will include:

(1) A description of the PHS Act requirements or the No Surprises Act requirements that CMS has determined the provider or facility violated.

(2) A description of any complaint or other information upon which CMS based its investigation, including the basis for determining the number of violations.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any circumstances described in § 150.513 that were considered when determining the amount of the proposed penalty.

(5) Instructions for responding to the notice, including:

(i) A specific statement of the provider or facility's right to a hearing; and

(ii) A statement that failure to request a hearing within 30 days of receipt of the notice permits the imposition of the proposed penalty without right of appeal in accordance with § 150.519.

(b) [Reserved]

§ 150.517 Hearing.

(a) The provisions found in §§ 150.401 through 150.457 shall apply to a hearing conducted under this subpart.

(b) Any provider or facility upon which CMS has proposed the imposition of a penalty may appeal such proposed penalty by requesting a hearing before an ALJ in accordance with § 150.405. The form and content of the request for a hearing must comply with § 150.407.

(c) If the provider or facility fails, within the time period permitted, to exercise the right to a hearing under this section, the proposed penalty becomes final.

§ 150.519 Failure to request a hearing.

If the provider or facility does not request a hearing within 30 days of the issuance of the notice described in § 150.515, or show good cause, as determined under § 150.405(b), for failing to timely exercise its right to a hearing, CMS may assess the proposed civil money penalty. CMS will notify the provider or facility in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of any penalty that has been assessed and of the means by which the provider or facility may satisfy the judgment. The provider or facility has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405.

§ 150.521 Collateral estoppel.

(a) Where a final decision pertaining to the provider or facility's liability for acts that violate this part has been rendered in any proceeding in which the provider or facility was a party and had an opportunity to be heard, the provider or facility shall be bound by such decision in any proceeding under this part.

(b) In a proceeding under this part, a provider or facility is estopped from denying the essential elements of a criminal offense if the proceeding:

(1) Is against a provider or facility which has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements; and

(2) Involves the same transactions as in the criminal action.

§ 150.523 Judicial review.

(a) Any provider or facility against which a final decision imposing a civil money penalty is entered by the ALJ pursuant to this subpart may obtain

review in the United States Court of Appeals for the circuit in which the person resides, or where the violation occurred, by filing in such court (within 60 days following the date on which such decision becomes final) a written petition requesting the decision be modified or set aside. Such review will be conducted pursuant to section 1128A(e) of the Social Security Act.

(b) A provider or facility must exhaust all administrative appeal procedures established under this part before the provider or facility may bring an action in Federal court, as provided in section 1128A(e) of the Social Security Act, concerning any penalty imposed pursuant to this part.

(c) Administrative remedies are exhausted on the date an ALJ's initial decision becomes final under § 150.453, or the date of the Administrator's decision affirming, reversing, modifying, or remanding the ALJ's initial decision under § 150.457, as applicable.

(d) After the clerk of the court transmits a copy of the petition

specified in paragraph (a) of this section to the Secretary, the Secretary will file in the Court the record in the proceeding as provided in section 2112 of Title 28, United States Code.

§ 150.525 Notice to other agencies.

Whenever a penalty becomes final, the Secretary will notify the following organizations and entities about such action and the reasons for it: The appropriate State or local medical or professional association, the State Department of Health, the appropriate State or local licensing agency or organization, and the appropriate utilization and quality control peer review organization. The Secretary may additionally notify the following entities, as appropriate: The State Department of Insurance or similar agency, the State Attorney General, the Secretary of Labor, the Secretary of the Treasury, or the Director of the U.S. Office of Personnel Management.

[FR Doc. 2021-19797 Filed 9-10-21; 5:00 pm]

BILLING CODE 6523-63-P; 4120-01-P; 4830-01-P; 4510-29-P