



OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206-AO30

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD9951]

RIN 1545-BQ04

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB99

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 147, 149, and 156

[CMS-9909-IFC]

RIN 0938-AU63

Requirements Related to Surprise Billing; Part I

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: Interim final rules with request for comments.

SUMMARY: This document sets forth interim final rules implementing certain provisions of the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021. These interim final rules amend and add provisions to existing rules under the Internal Revenue Code, the Employee Retirement Income Security Act, the Public Health Service Act, and the

Federal Employees Health Benefits Act. These interim final rules implement provisions of the No Surprises Act that protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at participating facilities, and air ambulance services from nonparticipating providers of air ambulance services, under certain circumstances. In this rulemaking, the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments) are issuing interim final rules with largely parallel provisions that apply to group health plans and health insurance issuers offering group or individual health insurance coverage. HHS is also issuing in this rulemaking additional interim final rules that apply to emergency departments of hospitals and independent freestanding emergency departments, health care providers and facilities, and providers of air ambulance services related to the protections against surprise billing. The Office of Personnel Management (OPM) is issuing in this rulemaking interim final rules that specify how certain provisions of the No Surprises Act apply to health benefits plans offered by carriers under the Federal Employees Health Benefits Act (FEHBA).

DATES: Effective date: These regulations are effective on [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

Applicability date: The regulations are generally applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The HHS-only regulations that apply to health care providers, facilities, and providers of air ambulance services are applicable beginning on January 1, 2022. The OPM-only regulations that apply to health benefits plans are applicable to contract years beginning on or after January 1, 2022.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **September 7, 2021**.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments and OPM. Please do not

submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, refer to file code CMS-9909-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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 at <https://www.regulations.gov> by entering the file code in the search window and then clicking on “Comment”.

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-9909-IFC,
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-9909-IFC,

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: Padma Babubhai Shah, Office of Personnel Management, at 202-606-4056; Kari DiCecco, Internal Revenue Service, Department of the Treasury, at 202-317-5500; Matt Litton or David Sydlik, Employee Benefits Security Administration, Department of Labor, at 202-693-8335; Lindsey Murtagh, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301-492-4106.

Customer Service Information: Information from OPM on health benefits plans offered under the Federal Employees Health Benefits (FEHB) Program can be found on the OPM website (www.opm.gov/healthcare-insurance/healthcare/). Individuals interested in obtaining information from the DOL concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL’s website (www.dol.gov/ebsa). In addition, information from HHS on private health insurance coverage and coverage provided by non-federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (www.cms.gov/cciiio), and information on health care reform can be found at www.HealthCare.gov.

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://regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

A. Patient Protections and Requirements Related to Emergency Services under Section 2719A of the Public Health Service Act

The Patient Protection and Affordable Care Act (Pub. L. 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 Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.¹ The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make 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 incorporated into ERISA and the Code.

Under section 2719A of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, if a non-grandfathered group health plan or health insurance issuer offering non-grandfathered group or individual health insurance coverage provides any benefits with respect to emergency services in an emergency department of a hospital, the plan or issuer must cover emergency services without the individual or the health care provider having to obtain prior authorization (including when the emergency services are provided out-of-network) and without regard to whether the health care provider furnishing the emergency services is an in-network provider with respect to the services. The emergency

¹ The term “group health plan” includes both insured and self-insured group health plans.

services must be provided without regard to any other term or condition of the plan or health insurance coverage other than the exclusion or coordination of benefits, an affiliation or waiting period permitted under the Code, ERISA, and the PHS Act, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services. In addition, carriers offering FEHB plans must comply with requirements described in section 2719A of the PHS Act in the same manner as they apply to a plan or issuer.

For purposes of the requirements under section 2719A of the PHS Act, emergency services mean, with respect to an emergency medical condition, (1) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and (2) that is within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of the Social Security Act to stabilize the patient.

Regulations implementing section 2719A of the PHS Act include these consumer protections.² Section 2719A of the PHS Act did not prohibit balance billing. 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). To avoid the circumvention of the protections of section 2719A of the PHS Act, in the implementing regulations, the Departments determined it was necessary that a reasonable amount be paid by a plan or issuer before a patient becomes

² 26 CFR 54.9815-2719A(b); 29 CFR 2590.715-2719A(b); 45 CFR 147.138(b).

responsible for a balance billing amount.³ Therefore, under the Departments' final regulations published in the **Federal Register** on November 18, 2015 (Patient Protections Final Rule), a plan or issuer satisfies the out-of-network emergency care cost-sharing limitations in the statute if it provides benefits for out-of-network emergency services in an amount at least equal to the greatest of the following three amounts (adjusted for in-network cost sharing): (1) the median amount negotiated with in-network providers for the emergency service; (2) the amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable (UCR) amount); or (3) the amount that would be paid under Medicare Part A or Part B for the emergency service (collectively, minimum payment standards).⁴ The Departments' regulations clarify that the cost-sharing requirements create a minimum payment requirement for the plan or issuer.⁵ The Departments also clarified that the cost-sharing requirements do not prohibit a group health plan or health insurance issuer from providing benefits with respect to an emergency service that are greater than the amounts specified in the regulations. However, those regulations address balance billing with respect to only emergency services and, even in that context, they serve only to minimize the amount of a balance bill by requiring that plans and issuers must pay a reasonable amount for emergency services before a patient becomes responsible for a balance billing amount. Prior to the enactment of the No Surprises Act, these minimum payment standards were the only federal consumer protections to reduce potential amounts of balance

³ 75 FR 37188, 37194 (June 28, 2010); *see also* 80 FR 72192 (Nov. 18, 2015). Additional clarification of these rules was also provided in 2018. *See* 83 FR 19431 (May 3, 2018).

⁴ 26 CFR 54.9815-2719A(b)(3); 29 CFR 2590.715-2719A(b)(3); 45 CFR 147.138(b)(3).

⁵ If state law prohibits balance billing, or in cases in which a group health plan or health insurance issuer is contractually responsible for balance billing amounts, plans and issuers are not required to satisfy the minimum payment standards set forth in the regulations, but may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in-network. *See* 26 CFR 54.9815-2719A(b)(3)(iii); 29 CFR 2590.715-2719A(b)(3)(iii); 45 CFR 147.138(b)(3)(iii); FAQs about Affordable Care Act Implementation (Part I), Q15 (Sept. 20, 2010), available at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs>; www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.

billing for individuals enrolled in group health plans and group and individual health insurance coverage.

The No Surprises Act added section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act, which expand the patient protections related to emergency services under section 2719A of the PHS Act, in part, by providing additional consumer protections related to balance billing.⁶ The No Surprises Act amended section 2719A of the PHS Act to include a sunset provision effective for plan years beginning on or after January 1, 2022, when the new protections under the No Surprises Act take effect.

Additionally, the No Surprises Act recodified the patient protections regarding choice of health care professional from section 2719A(a), (c), and (d) of the PHS Act at new section 9822 of the Code, section 722 of ERISA, and section 2799A-7 of the PHS Act. If a plan or issuer requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, these provisions permit individuals to designate any participating primary care providers available to accept them, including pediatricians, and prohibit the plan or issuer from requiring authorization or referral for obstetrical or gynecological care.

B. Surprise Billing and the Need for Greater Consumer Protections

Most group health plans, and health insurance issuers offering group or individual health insurance coverage, have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services.⁷ By contrast, providers and facilities that are not part of a plan or issuer's network (nonparticipating providers) usually charge higher amounts than the contracted rates that plans and issuers have negotiated with participating providers and facilities. When a participant,

⁶ These new protections apply regardless of whether the plan or coverage is a grandfathered health plan under section 1251 of the Affordable Care Act. The No Surprises Act also amended 5 U.S.C. 8902(p) to ensure that covered individuals enrolled in FEHB plans receive these protections.

⁷ These interim final rules refer to providers both in terms of their participation (participating provider) and in terms of a network (in-network provider). In both situations, the intent is to refer to a provider that has a contractual relationship or other arrangement with a plan or issuer to provide health care items and services for participants, beneficiaries, and enrollees of the plan or issuer.

beneficiary, or enrollee receives care from a nonparticipating provider, the individual's plan or issuer may decline to pay for the service or may pay an amount that is lower than the provider's billed charges, and may subject the individual to greater cost-sharing requirements than would have been charged had the services been furnished by a participating provider. Prior to the No Surprises Act, the nonparticipating provider could generally balance bill the individual for the difference between the provider's billed charges and the sum of the amount paid by the plan or issuer and the cost sharing paid by the individual, unless otherwise prohibited by state law.

A balance bill may come as a surprise for the individual. A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a covered person receives medical services from a provider or facility that, usually unknown to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage. Surprise billing occurs both for emergency and non-emergency care. In an emergency, a person usually goes (or is taken by emergency transport) to a nearby emergency department. Even if they go to a participating hospital or facility for emergency care, they may receive care from nonparticipating providers working at that facility. For non-emergency care, a person may choose a participating facility (and possibly even a participating provider), but not know that at least one provider involved in their care (for example, an anesthesiologist or radiologist) is a nonparticipating provider. In either circumstance, the person might not be in a position to choose the provider, or to ensure that the provider is a participating provider. Therefore, in addition to a bill for their cost-sharing amount, which tends to be higher for out-of-network services, the person might receive a balance bill from the nonparticipating provider or facility. This scenario also plays out frequently for air ambulance services, where individuals generally do not have the ability to select a provider of air ambulance services, and, therefore, have little or no control over whether the provider is in-network with their plan or coverage.

When individuals are unable to avoid nonparticipating providers, it raises health care costs and exposes patients to financial risk.⁸ The evidence suggests that the ability to balance bill is used as leverage by some providers to obtain higher in-network payments, which results in higher premiums, higher cost sharing for individuals, and increased health care expenditures overall.⁹ Studies have shown that surprise bills can be large. For example, a recent study found that physicians collected, on average, 65 percent of the total charged amount for emergency department visits that likely included surprise bills, compared to 52 percent of the total charged amount for emergency department visits that likely did not include surprise bills. The study also found that nine percent of the individuals who likely received surprise bills paid physicians an amount more than \$400, which may cause financial hardship to many individuals.¹⁰ In addition, out-of-network cost sharing and payments for surprise bills usually do not count towards an individual's deductible and maximum out-of-pocket expenditure limits. Therefore, individuals with surprise bills may have difficulty reaching those limits, even after a significant health care event.

Another study using claims data from a large commercial issuer for the period 2010-2016 found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and the incidence increased from 32.3 percent in 2010 to 42.8 percent in 2016. The average potential amount of surprise medical bills also increased from \$220 in 2010 to \$628 in 2016. During the same period, 37 percent of inpatient admissions to in-network hospitals

⁸ 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.

⁹ 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/>.

¹⁰ Biener, A. et al., Emergency Physicians Recover a Higher Share of Charges From Out-Of-Network Care Than From In-Network Care, *Health Affairs* 40, No. 4 (2021): 622-628.

resulted in at least one out-of-network bill, increasing from 26.3 percent in 2010 to 42 percent in 2016, and the average potential surprise medical bill increased from \$804 to \$2,040.¹¹

Although some states have enacted laws to reduce or eliminate balance billing, these efforts have created a patchwork of consumer protections. Even within a state that has enacted such protections, those protections typically apply only to individuals enrolled in individual and group health insurance coverage, as ERISA generally preempts state laws that regulate self-insured group health plans sponsored by private employers. In addition, states are limited in their ability to address surprise bills that involve an out-of-state provider.

Surprise medical bills can lead to medical debt for individuals who have difficulty paying their bills. The impact is most keenly felt by those communities experiencing poverty and other social risk factors, as surprise medical bills and medical debt can negatively affect individuals' abilities to eliminate debt and create wealth, and ultimately can affect a family for generations.¹² A recent survey reported that while 68 percent of respondents said that it was difficult to pay a surprise bill, the likelihood of such difficulty was higher for middle income respondents (77 percent) and African Americans (74 percent). In addition, while 11 percent of survey respondents were unable to pay the surprise bill, 21 percent of low income respondents, 19 percent of African Americans, and 17 percent of respondents in rural areas were unable to do so.¹³ In addition, individuals are often confused by medical bills. A 2016 survey found that 61 percent of individuals are confused by medical bills, and for 49 percent of individuals surveyed, the amount owed was a surprise.¹⁴ These challenges are exacerbated for underserved communities, which are more likely to experience poor communication, underlying mistrust of

¹¹ Sun EC, Mello MM, Moshfegh J, Baker LC, Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. *JAMA Intern Med.* 2019; 179(11):1543–1550 (2019). doi:10.1001/jamainternmed.2019.3451.

¹² Taylor, J. Racism, inequality, and health care for African Americans. The Century Foundation: Report (December 19, 2019). <https://tcf.org/content/report/racism-inequality-health-care-african-americans/>; Chavis, B. Op-Ed: Big insurance must help end surprise medical billing. *blackpressUSA* (February 24, 2020).

¹³ Families USA, Surprise Medical Bills, Results from a National Survey, November 2019. <https://familiesusa.org/wp-content/uploads/2019/11/Surprise-Billing-National-Poll-Report-FINAL.pdf>.

¹⁴ Gooch, Kelly. 61% of patients confused by medical bills, survey finds. *Becker's Hospital Review* (July 14, 2016). <https://www.beckershospitalreview.com/finance/61-of-patients-confused-by-medical-bills-survey-finds.html>.

the medical system, and lower levels of patient engagement than other populations.¹⁵ Effective, culturally, and linguistically tailored communication at appropriate literacy levels, coupled with policies that address the social risk factors and other barriers underserved communities face to accessing, trusting, and understanding health care costs and coverage, can reduce disparities and promote health equity.¹⁶

Communication among providers, plans, consumers, communities, and consumer advocates must be consistent with and reinforce all relevant consumer protections related to surprise bills. Such communication must be accessible, linguistically tailored, and at an appropriate literacy level. This includes compliance with requirements to provide effective communication for individuals with disabilities under the Americans with Disabilities Act of 1990,¹⁷ section 504 of the Rehabilitation Act of 1973¹⁸ and, where applicable, section 1557 of the Affordable Care Act,¹⁹ as well as compliance with race, color, and national origin protections under title VI of the Civil Rights Act of 1964²⁰ and section 1557 of the Affordable Care Act. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex (including sexual orientation and gender identity), age, or disability in covered health programs or activities, including requiring covered entities to take reasonable steps to ensure meaningful access for individuals with limited English proficiency.

¹⁵ See Butler S, Sherriff N. How poor communication exacerbates health inequities and what to do about it. Brookings Institution: Report (February 22, 2021). <https://www.brookings.edu/research/how-poor-communication-exacerbates-health-inequities-and-what-to-do-about-it/>; Hamel, L., Lopes, L., Muñana, C., Artiga, S., Brodie, M. Race, Health, and COVID-19: The Views and Experiences of Black Americans. Kaiser Family Foundation (October 2020). <https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf>; Shen M.J., Peterson E.B., Costas-Muñiz R. *et al.* The Effects of Race and Racial Concordance on Patient-Physician Communication: A Systematic Review of the Literature. *J. Racial and Ethnic Health Disparities* **5**, 117–140 (2018). <https://doi.org/10.1007/s40615-017-0350-4>.

¹⁶ Pérez-Stable EJ, El-Toukhy S. Communicating with diverse patients: How patient and clinician factors affect disparities. *Patient Educ Couns.* 2018;101(12):2186-2194. doi:10.1016/j.pec.2018.08.021; McNally, M. Confronting disparities in access to healthcare for underserved populations. MedCity News (February 22, 2021). <https://medcitynews.com/2021/02/confronting-disparities-in-access-to-healthcare-for-underserved-populations-in-2021/>

¹⁷ 42 U.S.C. 12101 *et seq.*

¹⁸ 29 U.S.C. 794 and 794d.

¹⁹ 42 U.S.C. 18116(a).

²⁰ 42 U.S.C. 2000d.

On January 20, 2021, President Biden issued Executive Order 13985, “On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,”²¹ directing that as a policy matter, the federal government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Executive Order 13985 also directs HHS to assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups. Consistent with Executive Order 13985, regulations issued pursuant to the No Surprises Act must ensure that communication from plans, issuers, providers, facilities, and providers of air ambulance services recognizes these inequities and upholds all relevant consumer protections. Regulations issued pursuant to the No Surprises Act should ensure that all individuals, particularly those from underserved and minority communities, trust and believe information they receive related to costs and network coverage. Regulations and policies should enable and encourage regulated entities to address barriers to accessing care, including mistrust of the health care system. They should also encourage entities to communicate with individuals in a language they can understand, in a respectful way that addresses cultural differences, and at an appropriate literacy level. To ensure all consumers, particularly those in minority and underserved communities, are able to understand and benefit from these consumer protections, deliberate attention must be paid to the unique barriers and challenges underserved communities face in understanding and accessing health care. The Departments seek comment from those who are members of, advocate for, and work with underserved communities regarding the impact of these interim final rules.

C. Preventing Surprise Medical Bills under the Consolidated Appropriations Act, 2021

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which included the No Surprises Act, was signed into law. The No Surprises Act provides federal

²¹ 86 FR 7009 (Jan. 25, 2021).

protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise bills arise most frequently.²²

The CAA added provisions that apply to group health plans and health insurance issuers in the group and individual market in a new Part D of title XXVII of the PHS Act, and also added new provisions to part 7 of ERISA, and subchapter B of chapter 100 of the Code. Section 102 of the No Surprises Act added section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act, which contain limitations on cost sharing, and requirements for initial payments for emergency services and for non-emergency services provided by nonparticipating providers at certain participating health care facilities. Section 103 of the No Surprises Act amended section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act to establish an independent dispute resolution (IDR) process that allows plans and issuers and nonparticipating providers and nonparticipating emergency facilities to resolve disputes over out-of-network rates. Section 105 of the No Surprises Act added section 9817 of the Code, section 717 of ERISA, and section 2799A-2 of the PHS Act, which contain limitations on cost sharing and requirements for initial payments to nonparticipating providers of air ambulance services, and allow plans and issuers and such providers of air ambulance services to access the IDR process. The CAA also amended the FEHBA, as discussed in more detail in section I.D. of this preamble.

The CAA provisions that apply to health care providers and facilities and providers of air ambulance services, such as cost-sharing requirements, 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.

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 IDR process (sections 103 and

²² Pub. L. 116-260.

105 of Division BB), patient protections through transparency and the patient-provider dispute resolution process (section 112), and price comparison tools (section 114). The Departments also intend to undertake rulemaking this year to propose the form and manner in which plans, issuers, and providers of air ambulance services would report information regarding air ambulance services (section 106). In addition, HHS intends to undertake rulemaking to implement requirements on health insurance issuers offering individual health insurance coverage or short-term, limited-duration insurance to disclose and report information regarding direct or indirect compensation provided to agents and brokers (section 202(c)), as well as provisions related to HHS enforcement of requirements on issuers, non-federal governmental group health plans, providers, facilities, and providers of air ambulance services.

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), and 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 rulemaking regarding some of these provisions might not occur until after January 1, 2022. The Departments note that any such rulemaking to fully implement these provisions will 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. The Departments intend to issue guidance in the near future regarding their expectations related to good faith compliance with these provisions.

D. Preventing Surprise Medical Bills for Federal Employees Health Benefits Plans

The No Surprises Act also amended the FEHBA, 5 U.S.C. 8901 *et seq.*, by adding a new subsection (p) to 5 U.S.C. 8902. Under this new provision, each FEHB Program contract must require a carrier to comply with provisions of sections 9816, 9817, and 9822 of the Code; sections 716, 717, and 722 of ERISA; and sections 2799A–1, 2799A–2, and 2799A–7 of the PHS Act (as applicable) in the same manner as they apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage. Likewise, the provisions of sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act apply to health care providers, facilities, and providers of air ambulance services with respect to covered individuals in FEHB plans in the same manner as they apply to participants, beneficiaries, or enrollees in group health plans or coverage offered by health insurance issuers.

OPM is charged with administering the FEHB Program and maintains oversight and enforcement authority with respect to FEHB health benefits plans, which are federal governmental plans. Generally, under 5 U.S.C. 8902(p), each FEHB contract must require a carrier to comply with certain PHS Act, ERISA, and Code requirements in the same manner as they apply to a group health plan or health insurance issuer.

II. Executive Summary

These interim final rules implement provisions of the No Surprises Act that: (1) apply to group health plans, health insurance issuers offering group or individual health insurance coverage, and carriers in the FEHB Program to provide protections against balance billing and out-of-network cost sharing with respect to emergency services, non-emergency services furnished by nonparticipating providers at certain participating health care facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services; (2) prohibit nonparticipating providers, health care facilities, and providers of air ambulance services from balance billing participants, beneficiaries, and enrollees in certain situations, and permit these providers and facilities to balance bill individuals if certain notice and consent

requirements in the No Surprises Act are satisfied; (3) require certain health care facilities and providers to provide disclosures of federal and state patient protections against balance billing; (4) recodify certain patient protections that initially appeared in the ACA and that the No Surprises Act applies to grandfathered plans; and (5) set forth complaints processes with respect to violations of the protections against balance billing and out-of-network cost sharing under the No Surprises Act.

These interim final rules 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. Among other requirements, these interim final rules require emergency services to be covered without any prior authorization, without regard to whether the health care provider 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. Additionally, emergency services include certain services in an emergency department of a hospital or an independent freestanding emergency department, as well as post-stabilization services in certain instances.

With respect to emergency services, air ambulance services furnished by nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating facilities, these interim final rules 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, as required by the No Surprises Act.

These interim final rules specify that cost-sharing amounts for such services furnished by nonparticipating emergency facilities and nonparticipating providers at participating facilities must be calculated based on one of the following amounts: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if

there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed charge or the plan's or issuer's median contracted rate, referred to as the qualifying payment amount (QPA). Cost-sharing amounts for air ambulance services provided by nonparticipating providers must be calculated using the lesser of the billed charge or the QPA, and the cost-sharing requirement that would apply if such services were provided by a participating provider.

Under these interim final rules, balance billing for services covered by the rules generally is prohibited, and the total amount to be paid to the provider or facility, including any cost sharing, is based on: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; (3) if there is no such applicable All-Payer Model Agreement or specified state law, an amount agreed upon by the plan or issuer and the provider or facility; or (4) if none of those three conditions apply, an amount determined by an IDR entity.

In general, under the No Surprises Act and these interim final rules, the protections that limit cost sharing and prohibit balance billing do not apply to certain post-stabilization services, or to certain non-emergency services performed by nonparticipating providers at participating health care facilities, if the provider or facility provides notice to the participant, beneficiary, or enrollee, and obtains the individual's consent to waive the balance billing protections. However, providers and facilities may not provide such notice or seek consent from individuals in certain circumstances where surprise bills are likely to occur, such as for ancillary services provided by nonparticipating providers in connection with non-emergency care in a participating facility. In such circumstances, balance billing is prohibited, and the other protections of the No Surprises Act, such as in-network cost-sharing requirements, continue to apply.

Neither the No Surprises Act, nor these interim final rules, universally protect individuals from every high or unexpected medical bill. For example, an individual may be enrolled in a group health plan or health insurance coverage that provides little or no coverage for their particular health care condition or the items and services necessary to treat that condition. In addition, balance billing continues to be permitted, unless prohibited by state law or contract, in circumstances where these interim final rules do not apply, such as for non-emergency items or services provided at facilities that are not included within the definition of health care facility in these interim final rules. Nonetheless, the No Surprises Act and these interim final rules provide relief from some of the more common scenarios where a participant, beneficiary, or enrollee might otherwise be faced with high and unexpected medical costs.

These interim final rules establish a complaints process for receiving and resolving complaints related to these new balance billing protections.

These interim final rules also implement the requirement of the No Surprises Act that certain health care providers and facilities make publicly available, post on a public website, and provide a one-page notice to individuals regarding: (1) the requirements and prohibitions applicable to the provider or facility under sections 2799B-1 and 2799B-2 of the PHS Act and their implementing regulations; (2) any applicable state balance billing requirements; and (3) how to contact appropriate state and federal agencies if the individual believes the provider or facility has violated the requirements described in the notice.

Section 116 of the No Surprises Act also added section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, which include similar disclosure requirements applicable to plans and issuers. In general, under these provisions, plans and issuers must make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act apply, information on the requirements applied under these aforementioned sections, as applicable; on

the requirements and prohibitions applied under sections 2799B-1 and 2799B-2 of the PHS Act; on other applicable state laws on out-of-network balance billing; and on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing. These disclosure requirements are applicable for plan years beginning on or after January 1, 2022. To reduce burden and facilitate compliance with these disclosure requirements, the Departments are concurrently issuing a model disclosure notice that health care providers, facilities, group health plans, and health insurance issuers may, but are not required to, use to satisfy the disclosure requirements regarding the balance billing protections. The Departments will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, if all other applicable requirements are met. In addition, HHS will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of section 2799B-3 of the PHS Act and 45 CFR 149.430, if all other applicable PHS Act requirements are met. The Departments may address the requirements under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, as added by the No Surprises Act, in more detail in future guidance or rulemaking. Until further guidance is issued, plans and issuers are expected to implement the requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act using a good faith, reasonable interpretation of the law. The Departments will take into account the statutory applicability date and the timeframe for implementation when determining good faith compliance with the law.

These interim final rules 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, as well as to health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022.

In the OPM interim final rules included in this rulemaking, OPM adopts all provisions of the Departments' interim final rules that address the sections of the Code, ERISA, and the PHS Act that are referenced in 5 U.S.C. 8902(p). In the OPM interim final rules, OPM defines terms unique to the FEHB Program, adapts some of the Departments' rules as necessary to properly integrate with the existing FEHB Program regulatory and contractual structure, sets forth the circumstances in which OPM will enforce these rules against FEHB carriers, and sets forth the types of court actions involving the FEHB Program that may be brought against OPM with respect to the No Surprises Act.

In effectuating compliance with 5 U.S.C. 8902(p), FEHB contract terms that relate to the nature, provision, or extent of coverage or benefits (including payments with respect to benefits) supersede and preempt state law or local law, or any regulation issued thereunder, which relates to health insurance or plans.²³ OPM contracts with FEHB carriers may include terms that adopt state law as governing for a particular purpose.

III. Overview of the Interim Final Rules – Departments of HHS, Labor, and the Treasury

A. Definitions

The provisions of the Code, ERISA, and the PHS Act added by the No Surprises Act, as well as these interim final rules, include defined terms that are specific to the requirements and implementation of the law. Definitions of these key terms are described throughout this preamble. These terms help define the scope of the balance billing protections and how cost-sharing amounts and payment levels are determined.

The Departments note that these interim final rules define the term “physician or health care provider” to mean a physician or other health care provider who is acting within the scope

²³ 5 U.S.C. 8902(m)(1); see *Coventry Health Care of Missouri, Inc. v. Nevils*, 137 S. Ct. 1190 (2017).

of practice of that provider's license or certification under applicable state law, but the definition specifically excludes providers of air ambulance services. The Departments recognize that, although the No Surprises Act does not define "provider," it uses the term in a manner that includes providers of air ambulance services in some provisions. For example, the No Surprises Act added section 2799B-4 of the PHS Act, which specifically includes providers of air ambulance services when referencing providers. However, certain other provisions in the No Surprises Act apply only to providers of air ambulance services, or apply to health care providers generally, but by their terms are inapplicable to providers of air ambulance services. As an example of the latter, the No Surprises Act added section 2799B-2 of the PHS Act, which generally prohibits balance billing by nonparticipating health care providers furnishing non-emergency services at participating health care facilities. Although this provision does not explicitly exclude providers of air ambulance services, providers of air ambulance services would not furnish non-emergency services at participating health care facilities. Therefore, the provision does not apply to providers of air ambulance services (such providers are, however, prohibited from balance billing under section 2799B-5 of the PHS Act). Similarly, section 2799B-3 of the PHS Act, which requires a health care provider to inform individuals of the requirements and prohibitions on such health care provider in sections 2799B-1 and 2799B-2 of the PHS Act (neither of which apply to providers of air ambulance services), does not by its terms apply to providers of air ambulance services. Therefore, these interim final rules define "physician or health care provider" to exclude providers of air ambulance services, in order to help clarify which provisions of the No Surprises Act and interim final rules apply to providers of air ambulance services. In instances where provisions under the No Surprises Act, as implemented in these interim final rules, apply to providers of air ambulance services, the provisions explicitly reference air ambulance providers. Conversely, where providers of air ambulance services are not explicitly mentioned, the provisions do not apply.

The Departments seek comment on the terms defined in these interim final rules, including the appropriateness and usability of the definitions, and whether additional terms should be defined in future rulemaking.

B. Preventing Surprise Medical Bills

1. Scope of the New Surprise Billing Protections

i. Emergency Services

Under section 9816(a) of the Code, section 716(a) of ERISA, and section 2799A-1(a) of the PHS Act, and these interim final rules, if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services as defined in these interim final rules and such coverage must be provided in accordance with these interim final rules.

A plan or issuer providing coverage of emergency services must do so without the individual or the health care provider having to obtain prior authorization (including when the emergency services are provided out-of-network) and without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition as defined in these interim final rules), an affiliation or waiting period as permitted under the Code, ERISA, or the PHS Act, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on coverage for emergency services received from nonparticipating providers or nonparticipating emergency facilities that is more restrictive than the requirements or limitations that apply to

emergency services received from participating providers or participating emergency facilities. In addition, such plan or health insurance coverage must comply with the requirements regarding cost sharing, payment amounts, and processes for resolving billing disputes described elsewhere in this preamble.

The terms “emergency medical condition,” “emergency services,” and “to stabilize” generally have the meaning given to them under the Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act.²⁴ Emergency services include: (1) an appropriate medical screening examination that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, including ancillary services routinely available to the emergency department, to evaluate whether an emergency medical condition exists; and (2) such further medical examination and treatment as may be required to stabilize the individual (regardless of the department of the hospital in which the further medical examination and treatment is furnished) within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department.

Under section 2719A of the PHS Act, emergency services were defined to include: (1) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and (2) such further medical examination and treatment as are required under section 1867 of the Social Security Act to stabilize the patient within the capabilities of the staff and facilities available at the hospital. HHS has previously interpreted the obligations on hospitals under EMTALA to provide medical examination and stabilization services to end when a patient is formally admitted in good faith.²⁵ Section 9816(a) of the Code, section 716(a) of ERISA, and section 2799A-1(a) of the PHS Act expand the definition of emergency services (as compared to

²⁴ 42 U.S.C. 1395dd.

²⁵ 42 CFR 489.24(a)(1)(ii); 68 FR 53221-53264 (Sept. 9, 2003); 73 FR 48654-48668 (Aug. 19, 2008).

section 2719A of the PHS Act) to include stabilization services “regardless of the department of the hospital in which the further medical examination and treatment is furnished.” Therefore, the definition of emergency services in these interim final rules includes pre-stabilization services that are provided after the patient is moved out of the emergency department and admitted to a hospital, and these services will be subject to the protections of the No Surprises Act.

Section 102 of the No Surprises Act further broadens the definition of emergency services to include emergency services provided at an independent freestanding emergency department. An independent freestanding emergency department is a health care facility (not limited to those described in the definition of health care facility at section 9816(b)(2)(A)(ii) of the Code, section 716(b)(2)(A)(ii) of ERISA, and section 2799A-1(b)(2)(A)(ii) of the PHS Act, as applicable) that provides emergency services, and is geographically separate and distinct from a hospital, and separately licensed as such by a state. The definition of “independent freestanding emergency department” is intended to include any health care facility that is geographically separate and distinct from a hospital, and that is licensed by a state to provide emergency services, even if the facility is not licensed under the term “independent freestanding emergency department.”

Regulation of health care facilities varies by state. In particular, state regulation of urgent care centers varies significantly, and is evolving as these types of centers become more common.²⁶ If under state licensure laws, urgent care centers are permitted to provide emergency services, then urgent care centers in that state that are geographically separate and distinct from a hospital would fall within the definition of independent freestanding emergency department for purposes of these interim final rules. In contrast, if state licensure of urgent care centers does not permit such facilities to provide emergency services as defined in these interim final rules, then urgent care centers in that state would not be treated as independent freestanding emergency

²⁶ Association of State and Territorial Health Officials. As Urgent Care Centers Increase, Licensing Authority Falling Under State Health Agencies, (Oct. 11, 2018) available at <https://www.astho.org/StatePublicHealth/As-Urgent-Care-Centers-Increase-Licensing-Authority-Falling-Under-State-Health-Agencies/10-11-18/>.

departments for purposes of these interim final rules. Finally, the definition of emergency services also includes additional post-stabilization services, as discussed in section III.B.1.ii of this preamble.

The term “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in EMTALA, including (1) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (2) serious impairment to bodily functions, or (3) serious dysfunction of any bodily organ or part.²⁷ This definition includes mental health conditions and substance use disorders.

The Departments are aware that some plans and issuers currently deny coverage of certain services provided in the emergency department of a hospital by determining whether an episode of care involves an emergency medical condition based solely on final diagnosis codes, such as International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes . In addition, some plans and issuers might automatically deny coverage based on a list of final diagnosis codes initially, without regard to the individual’s presenting symptoms or any additional review. Following an initial denial, plans and issuers might then provide for complete consideration of the claim, and apply the prudent layperson standard, only as part of an appeals process if the participant, beneficiary, or enrollee appeals. These practices are inconsistent with the emergency services requirements of the No Surprises Act and the ACA.²⁸ This is true even if the process for complete consideration of the claim following an initial denial

²⁷ See 42 U.S.C. 1395dd(e)(1)(A).

²⁸ See also *Am. Coll. of Emergency Physicians v. Blue Cross & Blue Shield of Georgia*, No. 20-11511, 2020 WL 6165852 (11th Cir. Oct. 22, 2020) (per curiam) (reversing dismissal of plaintiffs’ ACA and ERISA claims alleging defendants violated prudent layperson standard where review process was based upon physician review of medical records and diagnostic codes; prudent layperson standard ignores a patient’s final diagnosis and instead asks whether a person with average medical knowledge would reasonably think they need emergency services to address their symptoms).

is not designated as a formal appeal. Instead, the determination of whether the prudent layperson standard is met must be made on a case-by-case basis before an initial denial of an emergency services claim.

These interim final rules make clear that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services without limiting what constitutes an emergency medical condition (as defined in these interim final rules) solely on the basis of diagnosis codes. When a plan or issuer denies coverage, in whole or in part, for a claim for payment of a service rendered in the emergency department of a hospital or independent freestanding emergency department, including services rendered during observation or surgical services, the determination of whether the prudent layperson standard has been met must be based on all pertinent documentation and be focused on the presenting symptoms (and not solely on the final diagnosis). This determination must take into account that the legal standard regarding the decision to seek emergency services is based on whether a prudent layperson (rather than a medical professional) would reasonably consider the situation to be an emergency.²⁹ In covering emergency services, plans and issuers must also ensure that they do not restrict the coverage of emergency services by imposing a time limit between the onset of symptoms and the presentation of the participant, beneficiary, or enrollee at the emergency department. Similarly, plans and issuers also may not restrict the coverage of emergency services because the patient did not experience a sudden onset of the condition.

²⁹ However, nothing in the statute or these interim final rules prevents a plan or issuer from approving coverage for emergency services solely on the basis of diagnosis codes, or from taking diagnostic codes into account when deciding payment for a claim for emergency services, provided a denial of coverage is not based solely on diagnosis codes.

The Departments are also aware that some plans and issuers that generally provide coverage for emergency services have nonetheless denied benefits for such services based on other general plan exclusions. For example, the Departments are aware of some plans and issuers denying claims for emergency services provided to dependent women who are pregnant, based on a general plan exclusion for dependent maternity care. As explained previously, both the coverage of emergency services rules issued under section 2719A of the PHS Act and the new emergency services requirements included in these interim final rules provide, in part, that if a plan or issuer provides or covers any benefits with respect to services in an emergency department of a hospital (or under these interim final rules, in an independent freestanding emergency department), emergency services must be provided “without regard to any other term or condition of the plan or coverage (other than the exclusion or coordination of benefits...)” The Departments clarify that this provision does not permit plans and issuers to exclude benefits for items and services that would otherwise constitute benefits for an emergency medical condition as defined under these interim final rules. This provision does not permit plans and issuers that cover emergency services to deny benefits for a participant, beneficiary, or enrollee with an emergency medical condition that receives emergency services, based on a general plan exclusion that would apply to items and services other than emergency services.

ii. Post-Stabilization Services

Under section 9816(a)(3)(C)(ii) of the Code, section 716(a)(3)(C)(ii) of ERISA, and section 2799A-1(a)(3)(C)(ii) of the PHS Act, emergency services include any additional items and services that are covered under a plan or coverage and furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items and services are furnished) after a participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the other emergency services are furnished. Such additional items and services (referred to in this preamble as post-stabilization services) are considered emergency services

subject to surprise billing protections unless the conditions enumerated in section 9816(a)(3)(C)(ii)(II)(aa)-(cc) of the Code, section 716(a)(3)(C)(ii)(II)(aa)-(cc) of ERISA, or section 2799A-1(a)(3)(C)(ii)(II)(aa)-(cc) of the PHS Act, as applicable, are met, as well as such other conditions as specified by the Departments under paragraph (dd) of the respective sections. Therefore, these interim final rules provide that post-stabilization services are emergency services unless all of the following conditions are met.

First, the attending emergency physician or treating provider must determine that the participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into consideration the individual's medical condition. The HHS interim final rules codify this requirement at 45 CFR 149.410(b)(1). For this purpose, a treating provider is a physician or health care provider who has evaluated the individual. It is generally expected that a treating provider with medical training and experience related to the individual's specific medical condition will determine if the individual is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance. This determination is based on all the relevant facts and circumstances and the individual should be involved in the decision-making process, if possible. The determination by the attending emergency physician or treating provider is binding on the facility for purposes of this requirement. This requirement is based on the Departments' understanding that such provider is in the best position to make this determination.

For individuals receiving care in or near their plan's or issuer's covered service area, as well as individuals with coverage that uses a national network of providers and facilities, the statutory criterion would generally be sufficient to ensure that an individual can freely choose, based on their medical condition, to receive post-stabilization services at a participating facility or participating provider. The additional requirement in these interim final rules that the

individual be able to travel to an available participating provider or facility located within a reasonable travel distance, taking into consideration the individual's medical condition, is necessary and appropriate to carry out the provision of the No Surprises Act, as the requirement is intended to address the common situations in which an individual has received emergency services in a geographic region far from where any participating providers or facilities are located. In cases where the individual cannot travel using nonmedical transportation or nonemergency medical transportation, or cases where there are no participating facilities or participating providers located within a reasonable travel distance, taking into account the individual's medical condition, the Departments are of the view that individuals are unable to provide consent freely and, therefore, balance billing protections continue to apply.

In addition, the Departments recognize that an individual's transportation options may vary based on the individual's location, social risk, and other risk factors. In cases of underserved and geographically isolated communities and those with social risk factors related to income and transportation options, individuals may face additional barriers to obtaining post-stabilization services without a disruption in care. For example, individuals may not have the ability to pay for a taxi, may not have access to a car, may not be able to safely take public transit due to their medical condition, or may not have public transit options available. In these cases, the net effect would be the same: the individual would face unreasonable travel burdens that could prevent them from being able to consent freely to a waiver of the otherwise applicable balance billing protections. The Departments expect the attending emergency physician or treating provider to consider such factors when assessing the individual's ability to travel to a participating provider or facility. The Departments seek comment on the definition of "reasonable travel distance" and whether specific standards or examples should be provided regarding what constitutes an unreasonable travel burden. For example, should reasonable travel distance take into account only mileage, or also other factors, such as traffic or other route conditions that might make traveling difficult, time consuming, or hazardous?

In contrast to situations where a participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation following stabilization, in the event that the individual requires medical transportation to travel, including transportation by either ground or air ambulance vehicle, the individual is not in a condition to receive notice or provide consent. Therefore, the surprise billing protections continue to apply to post-stabilization services provided in connection with the visit for which the individual received emergency services.

Second, the provider or facility furnishing post-stabilization services must satisfy the notice and consent criteria of section 2799B-2(d) of the PHS Act with respect to such items and services (which are implemented in HHS-only interim final rules at 45 CFR 149.410(b)(2), and incorporate by reference the criteria for notice and consent in 45 CFR 149.420(c) through (g)).

Third, the individual (or the individual's authorized representative) must be in a condition to receive the information in the notice described in section 2799B-2 of the PHS Act (which is also implemented in 45 CFR 149.410(b)(3)) and to provide informed consent under such section, in accordance with applicable state law. Whether an individual is in a condition to receive the information in the notice is determined by the attending physician or treating provider using appropriate medical judgment. It is generally expected that an attending physician or treating provider with medical training and experience related to the individual's specific medical condition will make this determination based on all the relevant facts and circumstances. In addition to applying any requirements under state law, such medical professionals should apply the same principles as they would when determining if a patient is able to provide informed consent for treatment.³⁰ They should assess whether an individual is capable of understanding the

³⁰ Ethics guidance for physicians, published by the American Medical Association, states that physicians should “[a]ssess the patient’s ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision” as part of the process of seeking informed consent. American Medical Association, Code of Medical Ethics Opinion 2.1.1, available at <https://www.ama-assn.org/system/files/2019-06/code-of-medical-ethics-chapter-2.pdf> (last visited April 5, 2021). *See also* Gostin, LO. Public Health Law, 217-218 (2000) (discussing the four elements of the doctrine of informed consent: information, competency, voluntariness, and specificity).

information provided in the notice and the implications of consenting. Consideration must be given to the individual's state of mind after receiving the emergency services and the individual's emotional state at the time of consent. For example, consideration must be given to the effect of any alcohol or drug use by the individual, including the use or administration of prescribed medications, as well as to any pain the individual is experiencing, and the impact of those factors on the patient's state of mind. If the individual is experiencing a mental or behavioral health episode or displaying symptoms of a mental or behavioral health disorder, or is impaired by a substance abuse disorder, consideration should also be given as to whether the individual's condition impairs their ability to receive the information in the notice and provide informed consent. In addition, consideration must be given to cultural and contextual factors that may affect the informed decision-making and consent process for members of underserved communities, including lack of trust arising from historical inequities, misinformation about the informed consent process, or barriers to comprehension of the information given through the informed consent process and after the informed consent document is signed.³¹ These barriers may include accessibility, language, and literacy barriers. In addition, the informed consent must be obtained in a way that adheres to all civil rights protections cited within this rulemaking, ensuring that all individuals including those from underserved, underrepresented communities, with limited English proficiency, and with disabilities, are able to understand and freely make informed decisions.

Consent must be made voluntarily, meaning the individual must be able to consent freely, without undue influence, fraud, or duress. If post-stabilization services must be provided quickly after the emergency services are provided, it may be challenging for the individual or their authorized representative to have adequate time to make a clear-minded decision regarding consent. Consent obtained through a threat of restraint or immediacy of the need for treatment is

³¹ For a discussion of strategies to improve informed consent processes for minority communities, *see* Quinn, S.C., et al. Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys, *Journal of Empirical Research on Human Research Ethics*, 7(5): 44-55 (Dec. 2012).

not voluntary. In addition, the emergency physician or treating provider should consider whether the individual has reasonable options regarding post-stabilization services, transport, or service provider or facility. The Departments are of the view that the post-stabilization notice and consent procedures should generally be applied in limited circumstances, where the individual knowingly and purposefully seeks care from a nonparticipating provider or facility (such as deciding to go under the care of a specific provider or facility that the individual is familiar or comfortable with), and that the process should not be permitted to circumvent the consumer protections in the No Surprises Act.

Fourth, the provider or facility must satisfy any additional requirements or prohibitions as may be imposed under applicable state law. These interim final rules include this criterion recognizing that some state laws do not permit exceptions to state balance billing protections, such as allowing individuals to consent to waive protections. Thus, states may impose stricter standards by which post-stabilization services will be exempted from the surprise billing protections under these interim final rules, or states might not permit exceptions at all. This requirement is codified in the HHS interim final rules at 45 CFR 149.410(b)(5).

The No Surprises Act authorizes the Departments to specify other conditions that must be satisfied for post-stabilization services to be excepted from the definition of emergency services for purposes of the No Surprises Act. The Departments solicit comments on the conditions described earlier in this section. The Departments also seek comment on whether there are any additional conditions that would be appropriate to designate under the definition of emergency services, such as conditions relating to coordinating care transitions to participating providers and facilities. The Departments also solicit comments on what guidelines, beyond state laws regarding informed consent, may be needed to determine when an individual is in a condition to receive the written notice and provide consent. For example, are standards needed to account for individuals who are experiencing severe pain, intoxication, incapacitation, or dementia after being stabilized following an emergency medical condition?

iii. Non-Emergency Services Performed by Nonparticipating Providers at Participating Health Care Facilities

Section 9816(b) of the Code, section 716(b) of ERISA, section 2799A-1(b) of the PHS Act, and these interim final rules, apply surprise billing protections in the case of non-emergency services furnished by nonparticipating providers during a visit by a participant, beneficiary, or enrollee at a participating health care facility, unless the notice and consent requirements, as specified in these interim final rules, have been met.

Specifically, if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers benefits with respect to items and services (other than emergency services to which section 9816(a) of the Code, section 716(a) of ERISA, or section 2799A-1(a) of the PHS Act applies), the plan or issuer must cover such items and services furnished to a participant, beneficiary, or enrollee of the plan or coverage by a nonparticipating provider with respect to a visit at a participating health care facility in accordance with these interim final rules, including the requirements regarding cost sharing, payment amounts, and processes for resolving billing disputes described elsewhere in this preamble.

iv. Health Care Facilities

These interim final rules, consistent with section 9816(b)(2)(A) of the Code, section 716(b)(2)(A) of ERISA, and section 2799A-1(b)(2)(A) of the PHS Act, define a participating health care facility, in the context of non-emergency services, as a health care facility that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. These interim final rules also specify that a single case agreement between a health care facility and a plan or issuer, used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network

constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement with respect to the particular individual involved. Thus, when non-emergency services are furnished by a nonparticipating provider at a health care facility that has a single case agreement in place with respect to the individual being treated, as opposed to an agreement or contract that would apply to all the plan's or issuer's participants, beneficiaries, or enrollees, those non-emergency services would be subject to the protections described in 26 CFR 54.9816-5T, 29 CFR 2590.716-5, and 45 CFR 149.120, as applicable, and the corresponding requirements on providers at 45 CFR 149.420. The Departments are of the view that it is reasonable that an individual would expect items and services delivered at a health care facility that has a single case agreement in place with respect to the individual's care to be delivered on an in-network basis. Thus, these interim final rules apply the same protections in this circumstance as would apply at health care facilities that participate in the plan or issuer's network.³² The facility is considered a participating facility only with respect to items and services furnished to the individual whose care is covered by the single case agreement. Similarly, these interim final rules define a participating emergency facility to include a facility that has a single case agreement in place with a plan or issuer with respect to a specific individual's care. The Departments seek comment on this approach.

For this purpose, a health care facility described in the statute is each of the following, in the context of non-emergency services: (1) a hospital (as defined in 1861(e) of the Social Security Act); (2) a hospital outpatient department; (3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); or (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

In addition, section 9816(b)(2)(A)(ii)(V) of the Code, section 716(b)(2)(A)(ii)(V) of ERISA, and section 2799A-1(b)(2)(A)(ii)(V) of the PHS Act authorize the Departments to

³² In contrast, as discussed in section III.B.2.vi of this preamble, these interim final rules do not include negotiated rates under single-case agreements in the methodology for calculating the qualifying payment amount.

designate additional facilities as health care facilities. The Departments solicit comments on other facilities that would be appropriate to designate as health care facilities. The Departments are interested in comments identifying types of facilities in which surprise bills frequently arise, and are particularly interested in comments regarding whether urgent care centers or retail clinics should be designated as health care facilities for purposes of these interim final rules.

The Departments recognize that state regulation of urgent care centers varies significantly, as does the type of services they are permitted to provide under state law. Under these interim final rules, emergency services provided at urgent care centers that are licensed in a manner that brings them within the definition of independent freestanding emergency department would be subject to cost-sharing and balance billing protections, among others. However, given significant variation in state law definitions, urgent care centers are not included within the definition of health care facilities, in the context of non-emergency services. Thus, in cases where non-emergency services are furnished at participating urgent care centers by nonparticipating providers, those services would not receive the protections under these interim final rules. However, the Departments are of the view that it is possible that individuals may be using urgent care centers (regardless of how they are licensed) in a similar way to how they use independent freestanding emergency departments, in which case it may be appropriate to designate urgent care centers as health care facilities. The Departments seek comment on the degree to which individuals may be using urgent care centers in a similar way to how they use independent freestanding emergency departments. The Departments seek data on how frequently surprise bills arise in the context of urgent care centers. The Departments also seek comment on whether plans and issuers generally contract separately with urgent care centers and the providers who work at the centers, and how frequently contracting practices result in nonparticipating providers furnishing services at participating urgent care centers. The Departments also seek comment on potential definitions of the term urgent care center.

v. Items and Services within the Scope of a Visit

In addition to items and services furnished by a provider at the facility, a “visit” to a participating health care facility includes the furnishing of equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility. These services are not limited based on whether the provider furnishing the services is physically located at the facility. For example, if a sample is collected during an individual’s hospital visit and sent to an off-site laboratory, the laboratory services would be considered to be part of the individual’s visit to a participating health care facility, if laboratory services are covered by the plan or coverage. Similarly, if an individual receives a consultation with a specialist via telemedicine during a visit to a participating hospital, those telemedicine services would be considered part of the individual’s visit to a participating health care facility. The statutory definition of “visit” also provides authority for the Departments to specify other items and services. The Departments solicit comments regarding other items and services that would be appropriate to include within the scope of a visit for purposes of these interim final rules.

The No Surprises Act and these interim final rules provide for exceptions to the balance billing prohibitions and cost-sharing requirements if the participant, beneficiary, or enrollee is provided a compliant written notice and consents to receive such services from a nonparticipating provider at a participating health care facility. However, these exceptions do not apply with respect to certain ancillary services (in the context of non-emergency services) and other services under certain conditions, as discussed later in this preamble.

vi. Air Ambulance Services

Section 105 of the No Surprises Act added section 9817 of the Code, section 717 of ERISA, and section 2799A-2 of the PHS Act to address surprise air ambulance bills. These provisions apply in the case of a participant, beneficiary, or enrollee who receives services from a nonparticipating provider of air ambulance services, meaning medical transport by a rotary-wing air ambulance, as defined in 42 CFR 414.605, or fixed-wing air ambulance, as defined in

42 CFR 414.605. These interim final rules apply these provisions where a plan or coverage generally has a network of participating providers and provides or covers any benefits for air ambulance services, even if the plan or coverage does not have in its network any providers of air ambulance services. With respect to air ambulance services furnished by nonparticipating providers (including inter-facility transports), plans and issuers must comply with the requirements regarding cost sharing, payment amounts, and processes for resolving billing disputes described elsewhere in this preamble, if such services would be covered if provided by a participating provider with respect to such plan or coverage.

2. Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities

i. In General

Under section 9816(a) of the Code, section 716(a) of ERISA, section 2799A-1(a) of the PHS Act, and these interim final rules, if a plan or issuer provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the cost-sharing requirement for such services performed by a nonparticipating provider or nonparticipating emergency facility must not be greater than the requirement that would apply if such services were provided by a participating provider or a participating emergency facility. Additionally, if a plan or issuer provides or covers any benefits for non-emergency items and services furnished by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied certain notice and consent criteria with respect to such items and services, the plan or issuer may not impose a cost-sharing requirement for such items and services that is greater than the cost-sharing requirement that would apply had such items or services been furnished by a participating provider. Similarly, if a plan or issuer provides or covers benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider in such a manner that the cost-sharing requirement with respect to such services must be the same requirement that would apply if such services were provided by a participating

provider. For example, if a plan or issuer imposes a 20 percent coinsurance rate for emergency services from participating providers or participating emergency facilities, the plan or issuer may not impose a coinsurance rate on emergency services from nonparticipating providers or facilities that exceeds 20 percent. Stakeholders have reported that network participation rates are low among providers of air ambulance services. In instances where a plan or issuer does not have an established cost-sharing requirement that applies specifically to participating providers, the plan or issuer must calculate the cost-sharing amount using the generally applicable cost-sharing requirement for the relevant item or service under the plan or coverage.

Under sections 9816(a) and (b) and 9817(a) of the Code, sections 716(a) and (b) and 717(a) of ERISA, sections 2799A-1(a) and (b) and 2799A-2(a) of the PHS Act, and these interim final rules, any cost-sharing payments for emergency services, non-emergency services furnished by a nonparticipating provider in a participating health care facility, and air ambulance services furnished by a nonparticipating provider must be counted toward any in-network deductible or out-of-pocket maximums applied under the plan or coverage (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable), respectively (and these in-network deductibles and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to services furnished by a participating provider or facility.

ii. Cost-Sharing Amount

Section 9816(a)(1)(C)(iii) of the Code, section 716(a)(1)(C)(iii) of ERISA, section 2799A-1(a)(1)(C)(iii) of the PHS Act, and these interim final rules also specify that for emergency services furnished by a nonparticipating emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such services, as defined by the statute and in these interim final rules.

The “recognized amount” is: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no applicable All-Payer Model Agreement or specified state law, the lesser of the amount billed by the provider or facility or the QPA, which under these interim final rules generally is the median of the contracted rates of the plan or issuer for the item or service in the geographic region.

By requiring plans and issuers to calculate the cost-sharing amount using the recognized amount, rather than the amount the plan or issuer ultimately pays the nonparticipating provider or nonparticipating emergency facility for the furnished items or services, the No Surprises Act and these interim final rules limit the effect of provider-payer disputes about payment amounts on participant, beneficiary, or enrollee cost sharing. Under the statute and these interim final rules, the provider or facility and plan or issuer separately determine the total payment amount for the furnished items or services, but that amount generally does not affect the cost-sharing amount the individual must pay.

The Departments are aware that there may be some instances where a nonparticipating health care provider or facility might bill a plan or issuer for an item or service that is subject to these surprise billing protections in an amount less than the QPA. For example, this might be a relatively common occurrence for items whose patent expires after 2019, in instances where the QPA is based off the median of the contracted rates from 2019. In these instances, assuming the plan or issuer would not pay more than the billed charge, calculating cost sharing based on the QPA would require a participant, beneficiary, or enrollee to pay a higher percentage in cost sharing than if the items or services had been furnished by a participating provider. However, section 9816(a)(1)(C)(ii) of the Code, section 716(a)(1)(C)(ii) of ERISA, and section 2799A-1(a)(1)(C)(ii) of the PHS Act expressly prohibit plans and issuers from applying a cost-sharing requirement that is greater than the requirement that would apply if such services were provided by a participating provider or a participating emergency facility. Therefore, under these interim

final rules, in circumstances where a specified state law or All-Payer Model Agreement does not apply to determine the cost-sharing amount, cost sharing must be based on the lesser of the QPA or the amount billed by the provider for the item or service. The different methods for determining the recognized amount are discussed in separate sections of this section III.B.2 of this preamble.

With respect to air ambulance services furnished by nonparticipating providers, the recognized amount is not used for purposes of determining cost sharing. Rather, the statute specifies that the cost-sharing requirement with respect to such services must be the same requirement that would apply if such services were provided by a participating provider, and any coinsurance or deductible must be based on rates that would apply for such services if they were furnished by a participating provider. These interim final rules require that plans and issuers base any coinsurance and deductible for air ambulance services provided by a nonparticipating provider on the lesser of the QPA or the billed amount. The Departments have concluded that this policy is consistent with the statute's general intent to protect participants, beneficiaries, and enrollees from excessive bills, and to remove the individuals as much as possible from disputes between plans and issuers and providers of air ambulance services. In addition, using the QPA is one method of ensuring that any coinsurance or deductible is based on rates that would apply for the services if they were furnished by a participating provider, given that the QPA is generally based on median contracted rates, as opposed to rates charged by nonparticipating providers, and is one basis used for determining the cost-sharing amount in the context of emergency services and items and services furnished by nonparticipating providers at participating health care facilities.

As discussed in this preamble, the Airline Deregulation Act of 1978 (ADA) broadly preempts state laws that relate to air ambulance providers, and the Departments are unaware of any instances in which an All-Payer Model Agreement or a specified state law might apply. In addition, since an All-Payer Model Agreement or a specified state law would not need to follow

an approach based on rates that would apply for such services if they were furnished by a participating provider (for example, Medicare rates could be used instead), it is the Departments' view that Congress did not intend to apply the concept of the recognized amount to nonparticipating providers of air ambulance services. The Departments seek comment on any potential alternate approaches for calculating the cost-sharing amount for air ambulance services furnished by nonparticipating providers of air ambulance services.

iii. Out-of-Network Rate

In addition to establishing requirements related to cost sharing, the No Surprises Act and these interim final rules also establish requirements related to the total amount paid by a plan or issuer for items and services subject to these provisions, referred to as the out-of-network rate. The plan or issuer must make a total payment equal to one of the following amounts, less any cost sharing from the participant, beneficiary, or enrollee: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; (3) in the absence of an applicable All-Payer Model Agreement or specified state law, if the plan or issuer and the provider or facility have agreed on a payment amount, the agreed on amount; or (4) if none of those three conditions apply, and the parties enter into the IDR process and do not agree on a payment amount before the date when the IDR entity makes a determination of the amount, the amount determined by the IDR entity. These four approaches for determining the out-of-network rate are discussed more fully later in this preamble.

The requirements related to cost sharing and to the out-of-network rate apply when a group health plan or coverage provides or covers benefits for services subject to these provisions. The Departments interpret this to mean that the requirements apply when a plan or issuer provides coverage for such items and services, pursuant to the terms of the plan or coverage,

even in cases where an individual has not satisfied their deductible.³³ Because the cost-sharing amount is calculated using the recognized amount (or for air ambulance services the lesser of the QPA or the billed amount) that is calculated separately from the determination of the out-of-network rate, these requirements may result in circumstances where a plan or issuer must make payment prior to an individual meeting their deductible. Specifically, where the surprise billing protections apply, and the out-of-network rate exceeds the amount upon which cost sharing is based, a plan or issuer must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount (the latter of which in this case would equal the recognized amount, or the lesser of the QPA or the billed amount), even in cases where an individual has not satisfied their deductible, as illustrated in the following example.

Example. An individual is enrolled in a high deductible health plan with a \$1,500 deductible and has not yet accumulated any costs towards the deductible at the time the individual receives emergency services at an out-of-network facility. The plan determines that the recognized amount for the services is \$1,000. Because the individual has not satisfied the deductible, the individual's cost-sharing amount is \$1,000, which accumulates towards the deductible. The out-of-network rate is subsequently determined to be \$1,500. Under the requirements of the statute and these interim final rules, the plan is required to pay the difference between the out-of-network rate and the cost-sharing amount. Therefore, the plan pays \$500 for the emergency services, even though the individual has not satisfied the deductible. The individual's out-of-pocket costs are limited to the amount of cost-sharing originally calculated using the recognized amount (that is, \$1,000).

Although such a payment would generally cause a high deductible health plan to lose its status as a high deductible health plan, the No Surprises Act added section 223(c)(2)(F) to the Code to specify that a plan shall not fail to be treated as a high deductible health plan by reason

³³ Absent the balance billing protections under the No Surprises Act and these interim final rules, the plan or issuer would not generally be expected to make a payment to the provider or facility prior to an individual satisfying the deductible.

of providing benefits for medical care in accordance with section 9816 or 9817 of the Code, section 716 or 717 of ERISA, or section 2799A–1 or 2799A–2 of the PHS Act (the provisions added by the No Surprises Act related to surprise medical and air ambulance bills), or any state law providing similar protections to individuals, prior to the satisfaction of the deductible.³⁴

iv. Specified State Law

Under section 9816(a)(3)(I) of the Code, section 716(a)(3)(I) of ERISA, section 2799A-1(a)(3)(I) of the PHS Act, and these interim final rules, a specified state law is a state law that provides a method for determining the total amount payable under a group health plan or group or individual health insurance coverage to the extent the state law applies. This includes instances where the Departments have interpreted this term to include state laws where the state law applies because the state has allowed a plan that is not otherwise subject to applicable state law an opportunity to opt in to a program established under state law, subject to section 514 of ERISA, for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility. In cases where a specified state law applies, the recognized amount (the amount upon which cost sharing is based) and out-of-network rate for emergency and non-emergency services subject to the surprise billing protections is calculated based on such specified state law.

In order for a state law to determine the recognized amount or out-of-network rate, any such law must apply to: (1) the plan, issuer, or coverage involved, including where a state law applies because the state has allowed a plan that is not otherwise subject to applicable state law an opportunity to opt in, subject to section 514 of ERISA; (2) the nonparticipating provider or nonparticipating emergency facility involved (and in the case of state out-of-network rate laws, the nonparticipating provider of air ambulance services involved); and (3) the item or service involved. In instances where a state law does not satisfy all of these criteria, the state law does

³⁴ See section IV.A.5 of this preamble for a discussion of HHS-only interim final rules addressing catastrophic plans' compliance with these requirements.

not apply to determine the recognized amount or out-of-network rate. For example, where a particular state surprise billing law that governs the recognized amount and out-of-network rate applies to a particular plan or coverage but does not apply to nonparticipating neonatologists, who provide a specified ancillary service under section 2799B-2(b)(2) of the PHS Act, the consumer protections under federal law would determine the recognized amount and out-of-network rate with respect to neonatology services while the state law would apply with respect to other provider specialties covered under that state law. Similarly, where a state’s surprise billing laws apply only to health maintenance organizations (HMOs), federal protections against surprise billing would govern with respect to other types of coverage while the state protections would apply to HMOs for purposes of determining the recognized amount and out-of-network rate.

The same definition of “out-of-network rate”— including the reference to specified state laws—applies to air ambulance services as to other services. The Departments note, however, that the ADA states in relevant part: “...a State, political subdivision of a State, or political authority of at least 2 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.”³⁵ Assuming that a provider of air ambulance services is an “air carrier” covered by this provision, as is typical,³⁶ the provision preempts state laws that would limit the amount of payment that the provider of air ambulance services would otherwise be entitled to receive.³⁷ Given the applicability of the ADA, the Departments are not aware of any state laws that would meet the criteria to set the out-of-network rate for nonparticipating

³⁵ 49 U.S.C. 41713(b).

³⁶ An air ambulance provider is a covered “air carrier” if it has economic authority from the Department of Transportation to provide interstate air transportation. Most air ambulance providers have such authority under the provisions of 14 CFR Part 298. *See, e.g., Scarlett v. Air Methods Corp.*, 922 F.3d 1053 (10th Cir. 2019); *Air Evac EMS v. Cheatham*, 910 F.3d 751 (4th Cir. 2018).

³⁷ *See, e.g., Guardian Flight LLC v. Godfread*, 991 F.3d 916, 921 (8th Cir. 2021) (holding that ADA preempted state law prohibiting out-of-network air ambulance providers 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 air ambulance providers from collecting more than amount specified in fee schedule).

providers of air ambulance services when providing services subject to the protections in the No Surprises Act.

The Departments also seek comment on whether health insurance issuers, health care providers, or health care facilities, in instances where they are not otherwise subject to a specified state law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage, should have an opportunity, for purposes of these interim final rules, to opt in to a program established under state law, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility. The Departments seek comment on whether this approach would allow for more flexibility for state laws to apply when, for example, by their terms, they apply to the health insurance issuer and item and service in question, but not to the provider; whether an issuer, provider, or facility would still be subject to any specified state laws in their “home” state if they opt in to a program established under another state’s law; and whether an issuer, provider, or facility should be permitted to opt in on an episodic basis. The Departments are concerned that allowing providers and facilities to opt in to a program established under state law could increase health care prices if providers and facilities selectively opt in to state programs that favor providers and facilities in the determination of the out-of-network rate. The Departments seek comment on the potential impact of expanding the ability to opt in to a state program to providers and facilities. The Departments specifically seek comment from health insurance issuers, health care providers, or health care facilities located within or serving underserved and rural communities, and other communities facing a shortage of providers on the impact of these provisions on services, coverage, and payment for and within medically underserved, rural, and urban communities.

a. State Law Interaction with ERISA

Under the general preemption clause of section 514(a) of ERISA, state laws are preempted to the extent that they “relate” to employee benefit plans subject to title I of ERISA.

There are, however, a number of exceptions to this broad preemption provision. Section 514(b)(2)(A), referred to as the “savings clause,” provides in pertinent part that “nothing in this title (title I of ERISA) shall be construed to exempt or relieve any person from any law of any State which regulates insurance” Additionally, the preemption provisions of section 731 of ERISA (implemented in 29 CFR 2590.731(a)) apply so that the requirements of part 7 of ERISA are not to be “construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a ‘requirement’ of a federal standard.” The conference report accompanying the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which applied this preemption standard to state laws with respect to its title I health insurance reform provisions, indicates that this preemption is intended to be the “narrowest” preemption of states’ laws.³⁸ States may therefore continue to apply state law requirements to issuers except to the extent they prevent the application of ERISA requirements. Additionally, states have significant latitude to impose requirements on issuers that are more restrictive than the federal law. State laws that impose comparable or additional requirements on health insurance issuers would generally constitute a “specified state law” notwithstanding section 514 of ERISA and would continue to apply.

While section 514(b)(2)(A) saves from ERISA preemption state laws regulating insurance, section 514(b)(2)(B) of ERISA, referred to as the “deemer clause,” provides that a state law “purporting to regulate insurance” generally cannot deem an employee benefit plan to be an insurance company (or in the business of insurance) for the purpose of regulating such a plan as an insurance company (section 514(b)(6)(A) creates a partial exception to the deemer clause for employee welfare benefit plans that are also multiple employer welfare arrangements (MEWAs)). Thus, to the extent that a state law has a “reference to” or an impermissible

³⁸ See House Conf. Rep. No. 104-736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

connection with ERISA plans (such as laws that govern the payment of benefits), these laws are preempted, to the extent they apply to self-insured plans sponsored by private employers.³⁹ However, section 514 of ERISA does not prevent states from expanding access to a state program and allowing self-insured, ERISA-covered plans to choose to voluntarily comply with it. For example, the Departments allowed such plans to comply with their obligations for external review under section 2719 of the PHS Act by voluntarily opting in to the state external review process.⁴⁰ Similarly, these interim final rules allow self-insured plans (including non-federal governmental plans) to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)-(d) of the Code, section 716(a)-(d) of ERISA, and section 2799A-1(a)-(d) of the PHS Act. A group health plan that opts in to such a state law must do so for all items and services to which the state law applies. Under these interim final rules, a self-insured plan that has chosen to opt in to a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted in to a specified state law, identify the relevant state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

b. Examples Involving Specified State Laws

The following examples illustrate how state laws may or may not apply. In each example, assume there is no applicable All-Payer Model Agreement that would determine the recognized amount or out-of-network rate.

Example 1. (i) Facts. A health insurance issuer licensed in State A covers a specific non-emergency service that is provided to an enrollee by a nonparticipating provider in a participating health care facility, both of which are also licensed in State A. State A has a law

³⁹ See *Gobeille v. Liberty Mutual Ins. Co.* 577 U.S. 312 (2015); *Egelhoff v. Egelhoff*, 532 U.S. 141 (2001).

⁴⁰ See, e.g., Technical Release 2010-01; 76 FR 37208, 37211 fn. 13 (June 24, 2011).

that prohibits balance billing for non-emergency services provided to individuals by nonparticipating providers in a participating health care facility, and provides for a method for determining the cost-sharing amount and total amount payable. The state law applies to health insurance issuers and providers licensed in State A. The state law also applies to the type of service provided.

(ii) Conclusion. In this Example 1, State A's law would apply to determine the recognized amount and the out-of-network rate.

Example 2. (i) Facts. Same facts as Example 1, except that the nonparticipating provider and participating health care facility are located and licensed in State B. State A's law does not apply to the provider, because the provider is licensed and located in State B.

(ii) Conclusion. In this Example 2, State A's law would not apply to determine the recognized amount and out-of-network rate. Instead, the lesser of the billed amount or QPA would apply to determine the recognized amount, and either an amount determined through agreement between the provider and issuer or an amount determined by an IDR entity would apply to determine the out-of-network rate.

Example 3. (i) Facts. An individual receives emergency services at a nonparticipating hospital located in State A. The emergency services furnished include post-stabilization services, as described in 26 CFR 54.9816-4T(c)(2)(ii), 29 CFR 2590.716-4(c)(2)(ii), and 45 CFR 149.110(c)(2)(ii). The individual's coverage is through a health insurance issuer licensed in State A, and the coverage includes benefits with respect to services in an emergency department of a hospital. State A has a law that prohibits balance billing for emergency services provided to an individual at a nonparticipating hospital located in State A and provides a method for determining the cost-sharing amount and total amount payable in such cases. The law applies to issuers licensed in State A. However, State A's law has a definition of emergency services that does not include post-stabilization services.

(ii) Conclusion. In this Example 3, State A's law would apply to determine the cost-sharing amount and out-of-network rate for the emergency services, as defined under State A's law. State A's law would not apply for purposes of determining the cost-sharing amount and out-of-network rate for the post-stabilization services. Instead, the lesser of the QPA or billed amount would apply to determine the recognized amount, and either an amount determined through agreement between the hospital and issuer or an amount determined by an IDR entity would apply to determine the out-of-network rate, with respect to post-stabilization services.

Example 4. (i) Facts. A self-insured plan, subject to ERISA, covers a specific non-emergency service that is provided to a participant by a nonparticipating provider in a participating health care facility, both of which are licensed in State A. State A has a law that prohibits balance billing for non-emergency services provided to individuals by nonparticipating providers in a participating health care facility, and provides for a method for determining the cost-sharing amount and total amount payable. The law applies to health insurance issuers and providers licensed in State A, and provides that plans that are not otherwise subject to the law may opt in. The law also applies to the type of service provided. The self-insured plan has opted in.

(ii) Conclusion. In this Example 4, State A's law would apply to determine the recognized amount and the out-of-network rate.

The Departments are of the view that it would be uncommon for laws of more than one state to each apply to the same health insurance issuer, and to the same provider for a particular item or service. Therefore, the Departments do not foresee many instances where there might be a question as to which state's law applies to determine the recognized amount or out-of-network rate. However, in such uncommon scenarios, one approach might be for the states involved to make that decision. Another approach might be that the law enacted by the state in which the service is provided would apply. Yet another approach would be for the QPA to apply to determine the recognized amount, and either a negotiated amount or an amount determined by an

IDR entity to apply to determine the out-of-network rate. The Departments seek comment on these and any other approaches for resolving this choice-of-law question. The Departments also seek comment on how states have handled such questions prior to the enactment of the No Surprises Act, should these types of conflicts exist.

The Departments are of the view that Congress intended that where state law provides a method for determining the total amount payable under a plan or coverage, the state law regarding balance billing would govern, rather than the alternative method for determining the out-of-network rate under the No Surprises Act. The Departments interpret the statutory phrase “a State law that provides for a method for determining the total amount payable under such a plan, coverage, or issuer, respectively” broadly as referring not only to state laws that set a mathematical formula for determining the out-of-network rate, or that set a predetermined amount for an out-of-network item or service. Rather, the Departments interpret that language to also include, for example, state laws that require or permit a plan or issuer and a provider or facility to negotiate, and then to engage in a state arbitration process to determine the out-of-network rate. Such state laws provide a process for determining the total amount payable, and in such instances, the timeframes and processes under such a state law related to negotiations and arbitration would apply, as opposed to the timeframes and IDR process under the No Surprises Act.

In addition, the Departments are of the view that Congress did not intend for the No Surprises Act to preempt provisions in state balance billing laws that address issues beyond how to calculate the cost-sharing amount and out-of-network rate. To the extent state laws do not prevent the application of a federal requirement or prohibition on balance billing, the Departments are of the view that such state laws are consistent with the statutory framework of the No Surprises Act and would not be preempted.⁴¹ This view extends to any state law that

⁴¹ Section 731(a) of ERISA and section 2724(a) of the PHS Act. As noted above, the HIPAA conference report indicates that this preemption standard is intended to be the “narrowest” preemption of states’ laws. *See* House Conf. Rep. No. 104-736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

provides balance billing protections beyond what these interim final rules provide. In fact, Congress specifically indicated that such state balance billing laws may continue in effect along with the balance billing protections set forth in the statute, by requiring in new section 2799B-3 of the PHS Act that providers must disclose to participants, beneficiaries, and enrollees information about federal balance billing protections, plus any other protections that apply under state law. A more detailed discussion of the disclosure requirements appears in section IV.A.3 of this preamble, which discusses the provisions codified in 45 CFR 149.430.

v. All-Payer Model Agreements

As described earlier, in instances where an All-Payer Model Agreement is applicable, the recognized amount (the amount upon which cost sharing is based with respect to items and services furnished by nonparticipating emergency facilities, and nonparticipating providers of nonemergency items and services in participating facilities) and the out-of-network rate are determined using the amount that the state approves under the All-Payer Model Agreement for such items or services.

An All-Payer Model Agreement is an agreement between the Centers for Medicare & Medicaid Services (CMS) and a state to test and operate systems of all-payer payment reform for the medical care of residents of the state, under the authority granted under section 1115A the Social Security Act. Under the terms of section 1115A of the Social Security Act, such Agreements may waive specific provisions of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for the purposes of testing the Model. All-Payer Model Agreements can vary significantly by state, including in using different approaches for approving payment amounts for items or services covered by the Agreements. The Departments are of the view that it is important to maximally preserve states' abilities to test all-payer payment reform through these Agreements, including their abilities to do so using varied approaches to setting payment amounts. These interim final rules defer to the state to determine the circumstances

under which, and how, it will approve an amount for an item or service under a payment system established by an All-Payer Model Agreement. Participating in an all-payer model governed by an All-Payer Model Agreement may be voluntary or mandatory for a given payer; the system of all-payer payment reform may apply statewide or only in certain regions, such as rural regions; and payments under the system of all-payer payment reform may apply only to certain providers or facilities and certain items and services.⁴² To account for potential variations among All-Payer Model Agreements, the Departments are proposing to take a similar approach that these interim final rules establish with respect to state laws. Specifically, in order for an All-Payer Model Agreement to determine the recognized amount or out-of-network rate, any such Agreement must apply to the coverage involved; to the nonparticipating provider or nonparticipating emergency facility involved (and in the case of the out-of-network rate, to the nonparticipating provider of air ambulance services involved); and to the item or service involved. In instances where an All-Payer Model Agreement does not satisfy all of these criteria, the Agreement does not apply to determine the recognized amount or out-of-network rate, and, unless a specified state law applies, the recognized amount would be determined by the QPA (or the billed charge if less than the QPA), and the out-of-network rate would be the amount determined through agreement between the provider or facility and plan or issuer or the IDR process.

Under these interim final rules, an All-Payer Model Agreement is treated as applicable to a given provider or facility and plan or issuer if the terms of the Agreement, or any agreements described in that Agreement, are binding upon the provider, facility, plan, or issuer, which may occur through different mechanisms. For example, under the All-Payer Model Agreement for the Maryland Total Cost of Care Model and under the Maryland state all-payer law, all payers (including group health plans and health insurance issuers offering group or individual health

⁴² See, e.g., CMS. Vermont All-Payer ACO Model, (updated Apr. 8, 2020) available at <https://innovation.cms.gov/innovation-models/vermont-all-payer-aco-model>; CMS. Pennsylvania Rural Health Model, (updated Jan. 1, 2021) available at <https://innovation.cms.gov/innovation-models/pa-rural-health-model>; CMS. Maryland Total Cost of Care Model available at <https://innovation.cms.gov/innovation-models/md-tccm>.

insurance coverage) pay the amount determined under the Agreement with respect to hospital services covered by the Agreement.⁴³ However, the Agreement generally does not apply to the amount paid to a provider, such as a physician, who furnishes services at a hospital. In Maryland, therefore, the recognized amount and out-of-network rate would be set by the All-Payer Model Agreement for all plans and issuers for hospital charges covered under the Agreement. But, the All-Payer Model Agreement would generally not be used to set the recognized amount or out-of-network rate with respect to a nonparticipating provider's charges, unless the All-Payer Model Agreement, or any agreements described in that Agreement, specify the payment amount in a particular instance.

Although under state law plans and issuers in Maryland do not have discretion regarding whether to participate in the all-payer rate setting system under the Maryland Total Cost of Care Model, participation in other state-based models governed by All-Payer Model Agreements is voluntary. For example, under the All-Payer Model Agreement for the Vermont All-Payer Accountable Care Organization (ACO) Model, participation by providers, facilities, group health plans, and health insurance issuers is voluntary.⁴⁴ To the extent that both the provider or facility and plan or issuer has opted to participate in the Vermont All-Payer ACO Model and the Vermont All-Payer Model Agreement, or an agreement described in that Agreement, applies to a specific item or service, then that All-Payer Model Agreement would determine the recognized amount and out-of-network rate. But, for example, if a plan has opted to participate, but the provider furnishing the service has not, then the All-Payer Model Agreement would not be used to determine either the recognized amount or out-of-network rate. Instead, if a state law is applicable, the state law would apply. If no state law is applicable, then the recognized amount

⁴³ See CMS, Maryland Total Cost of Care Model, (updated Oct. 22, 2020) available at <https://innovation.cms.gov/innovation-models/md-tccm>. Under Maryland law, hospitals regulated by the Maryland Health Services Cost Review Commission (HSCRC) must charge payers the rates set by HSCRC, and payers, including group health plans and issuers offering individual or group health insurance, must pay the rates set by HSCRC. Maryland Code, Health-General Article §§ 19-212 and 19-219(a)(3) and (b)(2)(i) and Maryland Code, Insurance Article §15-604.

⁴⁴ <https://innovation.cms.gov/innovation-models/vermont-all-payer-aco-model>.

would be determined using the QPA,⁴⁵ and the out-of-network rate would be the amount agreed upon by the parties or determined through the IDR process established in the No Surprises Act, as discussed further elsewhere in this preamble.

vi. Methodology for Calculating the Qualifying Payment Amount

The No Surprises Act directs the Departments to establish through rulemaking the methodology that a group health plan or health insurance issuer offering group or individual health insurance coverage must use to determine the qualifying payment amount (QPA). As discussed earlier in this preamble, the No Surprises Act and these interim final rules require cost-sharing requirements imposed by plans and issuers in connection with emergency services furnished by a nonparticipating emergency facility or nonparticipating provider, or in connection with non-emergency services performed by nonparticipating providers at certain participating facilities to be based on the lesser of the billed charge or the QPA where an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified state law does not apply. In addition, IDR entities are directed by statute to consider the QPA when selecting between the offer submitted by a plan or issuer and the offer submitted by a facility or provider in order to determine the total payment for emergency services furnished by a nonparticipating emergency facility or nonparticipating provider, or non-emergency services performed by nonparticipating providers at certain participating facilities that are items and services subject to the IDR process.

In general, under section 9816(a)(3)(E) of the Code, section 716(a)(3)(E) of ERISA, and section 2799A-1(a)(3)(E) of the PHS Act, for a given item or service, the QPA is the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished, increased for inflation. The median

⁴⁵ See prior explanation regarding the requirement that when the surprise billing protections apply, in the event the billed charge is less than the recognized amount, cost sharing would be based on the billed charge.

contracted rate is determined with respect to all group health plans of the plan sponsor or all group or individual health insurance coverage offered by the health insurance issuer that are offered in the same insurance market, consistent with the methodology established by the Departments.

The No Surprises Act specifies an alternative methodology for determining the QPA in cases where a plan or issuer has insufficient information to calculate a median contracted rate for an item or service. The statute, however, envisions that these alternative methodologies, such as use of a third-party database, will be used in only limited circumstances where the plan or issuer cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region. Consistent with this statutory goal, these interim final rules generally seek to ensure that plans and issuers can meet the sufficient-information standard when determining the QPA and that use of alternative methodologies is minimized wherever possible.

The Departments seek comment on all aspects of the methodology established in these interim final rules for determining the QPA. In particular, the Departments seek comment on whether there are any considerations or factors that are not sufficiently accounted for in the methodology established in these interim final rules; the impact of the methodology on cost sharing, payment amounts, and provider network participation; and whether there are areas where commenters believe additional rulemaking or guidance is necessary. The Departments also seek comment as to the impact of large consolidated health care systems on contracted rates, and the impact of such contracted rates on prices and the QPA. The Departments are concerned that the contracting practices of such health care systems could inflate the QPA, and seek comment on whether adjustments to the QPA methodology are needed.

a. Median Contracted Rate

These interim final rules establish the methodology that plans and issuers must use to calculate the median of contracted rates. The plan or issuer will generally then apply an inflation adjustment to determine the QPA for items and services furnished in the relevant year.

In general, the median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all plans of the plan sponsor (or of the administering entity, if applicable) or all coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished, and selecting the middle number. These interim final rules define each of the relevant terms, as discussed in more detail in this section of the preamble.

In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. For example, assume the contracted rates for all plans of a sponsor in the same insurance market for a particular item or service provided by a provider in the same or similar specialty in a specified geographic region are \$475, \$490, and \$510. The median contracted rate for this service is \$490. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. If, in the previous example, there were a fourth contracted rate in the amount of \$515, the median contracted rate would be the average of the two middle amounts (\$490 and \$510), or \$500 $((\$490 + \$510) / 2)$. If the same amount is paid under two or more separate contracts, each contract is counted separately. Thus, in the previous example, if there were a fifth contracted rate also in the amount of \$515, the median contracted rate would be \$510, since there are two contracted rates below that amount (\$475 and \$490) and two contracted rates above that amount (\$515 and \$515).

Contracted Rate

The interim final rules define a “contracted rate” as the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and

services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.⁴⁶

The No Surprises Act envisions that each contracted rate for a given item or service be treated as a single data point when calculating a median contracted rate. Therefore, if a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate, if the same rate applies to all providers of such provider group or facility under the single contract. Likewise, the rate negotiated under a contract constitutes a single contracted rate regardless of the number of claims paid at that contracted rate. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider for a given item or service, each unique contracted rate constitutes a single contracted rate for purposes of determining the median contracted rate.⁴⁷ Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to other providers under separate contracts).

The Departments understand that some plans or issuers may rent provider networks or otherwise contract with third parties to manage provider networks. In these situations, contracted rates between providers and the entity responsible for managing the provider network on behalf of a plan or issuer would be treated as the plan's or issuer's contracted rates for purposes of calculating the QPA. The Departments seek comment on whether additional guidance or special rules are needed regarding how to define a contract in this situation.

⁴⁶ This definition is substantially similar to the definition of “negotiated rate” used for purposes of the transparency in coverage regulations at 26 CFR 54.9815–2715A1(a)(2)(xvi), 29 CFR 2590.715–2715A1(a)(2)(xvi), and 45 CFR 147.210(a)(2)(xvi).

⁴⁷ If a plan or issuer has a contract with multiple providers, with separate negotiated rates with several subgroups of providers, each unique contracted rate will generally constitute a single contracted rate for purposes of determining the median contracted rate. However, as discussed later in this section of the preamble, these interim final rules specify that if a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable. In such cases, the QPA for the particular item or service would take into account only the contracted rates for the applicable provider specialty, and would disregard other unique contracted rates under the same contract.

The Departments also understand that plans and issuers sometimes enter into special agreements with providers and facilities that generally are not otherwise contracted to participate in any of the networks of the plan or issuer. For example, a plan or issuer may negotiate an ad hoc arrangement with a nonparticipating provider or facility to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances. These interim final rules specify that solely for purposes of the definition of contracted rate, a single case agreement, letter of agreement, or other similar arrangement between a plan or issuer and a provider, facility, or provider of air ambulance services does not constitute a contract, and the rate paid under such an agreement should not be counted among the plan's or issuer's contracted rates. The term "contracted rate" refers only to the rate negotiated with providers and facilities that are contracted to participate in any of the networks of the plan or issuer under generally applicable terms of the plan or coverage and excludes rates negotiated with other providers and facilities. The Departments are of the view that this definition most closely aligns with the statutory intent of ensuring that the QPA reflects market rates under typical contract negotiations.⁴⁸

Insurance Market

In calculating the median contracted rate for a given item or service, the plan or issuer must take into account the contracted rates under all group health plans of the sponsor or all group or individual health insurance coverage offered by the issuer that are offered in the same insurance market.⁴⁹ The term "insurance market" for purposes of these interim final rules means one of the following: the individual market, small group market, or large group market (each as

⁴⁸ In contrast, as discussed earlier in this preamble, these interim final rules specify that a single case agreement constitutes a contractual relationship for purposes of the definition of participating health care facility and participating emergency facility. The Departments are of the view that it is reasonable that an individual would expect items and services delivered at a health care facility that has a single case agreement in place with respect to the individual's care to be delivered on an in-network basis, and therefore, that the balance billing protections should apply.

⁴⁹ The term "health insurance issuer" has the meaning given the term in section 2791(b) of the PHS Act, which, in relevant part, defines a health insurance issuer as an entity that is licensed to engage in the business of insurance in a state. Thus, an issuer is the licensed entity and the contracted rates of separate licensees under the same holding company are not taken into account.

defined under section 2791(e) of the PHS Act). The relevant insurance market is determined irrespective of the state. For example, in calculating the QPA for an item or service furnished to an enrollee in individual health insurance coverage, an issuer must take into account the contracted rates with providers or facilities in the applicable geographic region across the issuer's individual market offerings, inclusive of contracted rates for all individual health insurance coverage offered by the issuer in all states in which the issuer offers coverage in the individual market.

With respect to self-insured group health plans, these interim final rules define the term "insurance market" to mean all self-insured group health plans (other than account-based plans and plans that consist solely of excepted benefits) of the plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the QPA on behalf of the plan. The Departments understand that many self-insured group health plans are administered by entities other than the plan sponsor (such as a third-party administrator contracted by the plan) that would be responsible for calculating the QPA on behalf of the sponsor. To reduce the burden imposed on sponsors of self-insured group health plans, these interim final rules permit sponsors of self-insured group health plans to allow their third-party administrators to determine the QPA for the sponsor by calculating the median contracted rate using the contracted rates recognized by all self-insured group health plans administered by the third-party administrator (not only those of the particular plan sponsor). Under this approach, the Departments anticipate there will be fewer instances where a self-insured group health plan sponsor will lack sufficient information to calculate a median contracted rate for an item or service.

The Departments seek comment on the definition of insurance market with respect to self-insured group health plans and whether any contractual or other issues may prevent an entity, such as a third-party administrator, from using contracted rates from the different self-

insured plans it administers to calculate the QPA for a particular self-insured group health plan. DOL also seeks comment on the ability of self-insured group health plan fiduciaries to monitor the calculation of the QPA by the administering entities for compliance with the applicable requirements (for example, by ensuring the entities are using the correct contracted rates).

The Departments have determined that including rates negotiated under other more limited forms of coverage, such as excepted benefits, short-term, limited-duration insurance, and account-based plans, including health reimbursement arrangements, could skew the calculation of the median contracted rate, and these forms of coverage should not be included in the definition of the applicable insurance market. Furthermore, the definition of “qualifying payment amount” under section 2799A-1(a)(3)(E)(i)(I) of the PHS Act refers to individual health insurance coverage, and the term individual health insurance coverage, as defined under section 2791(b)(5) of the PHS Act, excludes short-term, limited-duration insurance.⁵⁰ Therefore, under these interim final rules, when referring to coverage offered by an issuer within the same insurance market for purposes of determining the QPA, the individual market excludes short-term, limited-duration insurance (as defined in 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103). In addition, under these interim final rules, all markets exclude 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). While excepted benefits can be offered in the individual or group markets, they are exempt from the federal insurance market reforms,⁵¹ and Congress amended the statutory exemption for these products to include the additional coverage provisions established under new Part D of title XXVII of the PHS Act.⁵² Account-based plans, including health reimbursement arrangements 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

⁵⁰ Since short-term, limited duration insurance is not individual health insurance coverage, it is also generally not subject to the federal individual market reforms. *See, e.g.*, 81 FR 75316 at 75317 (Oct. 31, 2016) and 83 FR 38212 at 38213 (Aug. 3, 2018).

⁵¹ Section 9831 of the Code, section 732 of ERISA, and sections 2722 and 2763 of the PHS Act.

⁵² These amendments add the phrase “and Part D” to section 2722(b), (c)(1), (c)(2), and (c)(3) of the PHS Act.

maximum fixed dollar amount for a period, such that the benefit design of these coverage options makes concepts related to surprise billing and choice of health care professionals inapplicable. Therefore, under these interim final rules, for purposes of calculating the QPA, all group markets similarly exclude coverage provided under account-based plans.

The Departments also clarify that any plan or coverage that is not a “group health plan” or “group or individual health insurance coverage” offered by a “health insurance issuer,” as those terms are defined in the Code, ERISA, and the PHS Act, such as a Medicare Advantage or Medicaid managed care organization plan, must also not be included in any insurance market for purposes of determining the QPA. This approach is consistent with the statutory requirement that the median contracted rate is determined with respect to all “group health plans” of the sponsor or all “group or individual health insurance coverage” offered by a health insurance issuer in the same insurance market.

Same or Similar Item or Service

Section 9816(a)(3)(E) of the Code, section 716(a)(3)(E) of ERISA, section 2799A-1(a)(3)(E) of the PHS Act, and these interim final rules provide that a plan or issuer must calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service. Under the interim final rules, the term “same or similar item or service” means a health care item or service billed under the same service code, or a comparable code under a different procedural code system. Service code means the code that describes an item or service, including a Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) code. A service code is a unique identifier, typically consisting of a string of numeric digits or alphanumeric characters, that corresponds to a standardized description, which is used to identify with specificity the item or service that was furnished to a patient. Different codes may be assigned to the same general service on the basis of certain variations in the provider’s method or approach, the complexity of the procedure or medical decision-making, and patient acuity level. Payers, providers, and

facilities understand these service codes and commonly use them for billing and paying claims (including for both individual items and services, and for items and services provided under a bundled payment arrangement). Thus, defining “same or similar item or service” by service code will make it easier for plans and issuers to calculate the QPA, and for providers and facilities to understand the QPA.

These interim final rules include specific requirements to account for modifiers (when applicable), which are codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed. For example, modifiers include hospital revenue codes, which indicate the department or place in the hospital in which a procedure or treatment is performed, as well as codes indicating whether services or procedures were performed by certain types of providers, such as physician assistants, nurse practitioners, certified registered nurse anesthetists, or assistant surgeons. In addition, modifiers can be used to indicate that the work required to provide a service in a particular instance was significantly greater – or significantly less – than the service typically requires. The Departments are of the view that it is important that the QPA methodology account for modifiers that affect payment rates under contracts with participating providers and facilities.

Under the methodology established in these interim final rules, plans and issuers must calculate separate median contracted rates for CPT code modifiers that distinguish the professional services component (“26”) from the technical component (“TC”). This will result in separate median contracted rates being calculated for services when billed by a facility versus a provider. In addition, where a plan’s or issuer’s contracted rates otherwise vary based on applying a modifier code, the plan or issuer must calculate a separate median contracted rate for each such service code-modifier combination. Modifiers that do not cause contracted rates to vary must not be taken into account when calculating the median contracted rate. These rules are intended to ensure that if a plan or issuer adjusts contracted rates with participating providers and

facilities based on modifier codes, those payment adjustments are appropriately reflected in the median contracted rate.

Provider in the Same or Similar Specialty

These interim final rules specify that if a plan or issuer has contracted rates for a service code that vary based on provider specialty, the median contracted rate is calculated separately for each provider specialty, as applicable. These interim final rules define “provider in the same or similar specialty” as the practice specialty of a provider, as identified by the plan or issuer consistent with the plan’s or issuer’s usual business practice. This definition is intended to provide plans or issuers with the flexibility necessary to calculate the median contracted rate, relying on their contracting practices with participating providers. If a plan’s or issuer’s usual business practice for identifying a provider’s practice specialty differs for contracting purposes and other business needs, the plan or issuer should use the method of identifying the practice specialty that it uses for contracting purposes.

The Departments considered requiring a plan or issuer to calculate separate median contracted rates for every provider specialty, but concluded that this approach would lead to more instances in which the plan or issuer would not have sufficient information to calculate the QPA using its contracted rates. In addition, the Departments understand that not all plans or issuers vary contracted rates by provider specialty, in which case requiring plans and issuers to calculate separate median contracted rates for each provider specialty would increase the burden associated with calculating the QPA without adding specificity to the QPA. Given that the No Surprises Act generally relies on using contracted rates to determine the QPA, the Departments conclude that plans and issuers should be required to calculate median contracted rates separately by provider specialty only where the plan or issuer otherwise varies its contracted rates based on provider specialty.

With respect to air ambulance services, all providers of air ambulance services (including inter-facility transports) are considered to be a single provider specialty for purposes of these

interim final rules. The Departments understand that contracted rates may vary depending on whether the air ambulance services are provided using a fixed-wing or rotary-wing aircraft. However, these distinctions based on vehicle type are accounted for in the QPA methodology established under these interim final rules through the use of service codes that are specific to fixed-wing or rotary-wing aircraft. Therefore, the Departments anticipate that median contracted rates for fixed-wing and rotary-wing aircraft would be determined separately based on the requirement under these interim final rules that median contracted rates be based on the contracted rates for the same or similar item or service, and concluded that it would be redundant to require plans and issuers to also calculate separate median contracted rates on the basis of vehicle type.

The Departments also understand that hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers. The Departments, however, are of the view that because participants, beneficiaries, and enrollees frequently do not have the ability to choose their air ambulance provider, they should not be required to pay higher cost-sharing amounts (such as coinsurance or a deductible) solely because the air ambulance provider assigned to them has negotiated higher contracted rates in order to cover its higher costs, or because it has a different revenue model, than other types of air ambulance providers. This approach is consistent with the approach these interim final rules take with respect to facilities, discussed in the following section of this preamble, which also generally does not provide for separate median contracted rates to be calculated based on characteristics of a particular facility. The Departments have concluded that this interpretation is consistent with the statute's intent to protect individuals from surprise medical bills.

Facility of the Same or Similar Facility Type

If a plan or issuer has contracted rates for emergency services that vary based on the type of facility (that is, whether a facility is an emergency department of a hospital or an independent freestanding emergency department), the median contracted rate is calculated separately for each

such facility type. Plans and issuers subject to the protections in the No Surprises Act are required to cover emergency services at both types of facilities. However, the Departments are aware that plans and issuers have not typically contracted with independent freestanding emergency departments, which may be a reflection of independent freestanding emergency departments' historical ability (prior to the enactment of the No Surprises Act) to charge higher rates for services furnished on an out-of-network basis, and to balance bill enrollees when the charges were denied in part or in full.⁵³ The Departments are also aware that there may be appreciable differences in the case-mix and level of patient acuity between these types of facilities.⁵⁴ Therefore, where a plan or issuer has established contracts with both hospital emergency departments and independent freestanding emergency departments, and its contracts vary the payment rate based on the facility type, the median contracted rate is to be calculated separately for each facility type. The Departments are of the view that this approach will maintain the ability of plans and issuers to develop QPAs that are appropriate to the different types of emergency facilities specified by statute. The Departments seek comment on this approach, and whether it would be more appropriate for plans and issuers to always calculate separate QPAs for hospital emergency departments and independent freestanding emergency departments regardless of whether the plan or issuer varies the payment rate based on facility type, or whether a plan or issuer should never calculate separate QPAs for hospital emergency departments and independent freestanding emergency departments.

However, these interim final rules do not allow plans or issuers to separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary, such as whether a hospital is an academic medical center or teaching hospital.

Given that participants, beneficiaries, and enrollees with emergency medical conditions typically

⁵³ See Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, ch. 8, Stand-alone Emergency Departments, June 2017, available at http://www.medpac.gov/docs/default-source/reports/jun17_ch8.pdf (last visited June 19, 2021).

⁵⁴ See *id.*

go (or are taken) to the nearest or most convenient emergency department, the Departments are of the view that, individuals generally should not be required to pay higher cost sharing (such as coinsurance or a deductible) based on features of the emergency facility that may have a bearing on its contracted rate with plans and issuers, but which are unrelated or incidental to the facility's role as a provider of emergency services.

Geographic Regions

Under the No Surprises Act, plans and issuers must calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service provided in the geographic region in which the item or service is furnished. The No Surprises Act directs the Departments, in consultation with the National Association of Insurance Commissioners (NAIC), to establish through rulemaking the geographic regions to be applied when determining the QPA, taking into account access to items and services in rural and underserved areas, including health professional shortage areas, as defined in section 332 of the PHS Act.⁵⁵

In consulting on the geographic regions to be applied under the No Surprises Act, the NAIC recommended that geographic regions correspond to the applicable rating area used for purposes of the individual market and small group market rating rules under section 2701 of the PHS Act, implemented at 45 CFR 147.102, while allowing states the flexibility to establish alternative geographic regions. However, some states define rating area by county, resulting in large numbers of rating areas in a state, some of which might include very few, if any, facilities and providers. Therefore, adopting the rating area definitions as the standard for geographic regions could lead to a large number of geographic regions for which a plan or issuer would have to calculate separate median contracted rates, a large number of geographic regions without

⁵⁵ Under section 332 of the PHS Act, a health professional shortage area is (A) an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary of HHS determines has a health manpower shortage and which is not reasonably accessible to an adequately served area, (B) a population group which the Secretary determines has such a shortage, or (C) a public or nonprofit private medical facility or other public facility which the Secretary determines has such a shortage. All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 254g of title 42 shall be automatically designated as having such a shortage.

sufficient information, as well as a large number of geographic regions in which the median contracted rate is influenced by outliers.

After consultation with the NAIC, the Departments are establishing geographic regions under these interim final rules that reflect differences in health care costs based on whether care is provided in urban or rural areas. The Departments are of the view that these geographic regions take into account access to items and services in rural and underserved areas, including health professional shortage areas, as defined at section 332 of the PHS Act. The Departments intend to monitor the effect of these geographic regions and periodically update such regions, as appropriate, taking into account the findings of the report submitted under section 109(a) of the No Surprises Act, which addresses, among other things, access to health care items and services in rural areas and health professional shortage areas.

In defining “geographic regions,” the Departments have sought not only to minimize instances in which a plan or issuer lacks sufficient information to calculate the median of contracted rates in any particular geographic region, but also to limit the instances in which a plan or issuer has only the minimum amount of information to meet the sufficient information standard, as discussed later in this preamble. Using larger geographic regions, for which plans and issuers are likely to have more information, is expected to reduce the likelihood that the median of contracted rates would be skewed by contracts under which the parties have agreed to particularly high or low payment amounts.

Under these interim final rules, for items and services other than air ambulance services, a geographic region is generally defined as one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state. The delineations for MSAs are described by the U.S. Office of Management and Budget (OMB) and published by the U.S. Census Bureau.⁵⁶ MSAs encompass at least one urbanized area with a population of 50,000

⁵⁶ OMB Bulletin No. 20-01. “Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas” (Mar. 6, 2020),

or more people, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. MSAs are always established along county boundaries, but may include counties from more than one state. Under this definition, MSAs that cross state boundaries are divided between the respective states, with all the counties in a particular MSA in each state counted as a geographic region.

However, under this definition, if a plan or issuer does not have sufficient information to calculate the median of contracted rates for an item or service provided in an MSA, the plan or issuer must consider all MSAs in the state to be a single region when calculating the median of contracted rates for the item or service provided in that MSA. In such cases, all MSAs in the state will constitute one geographic region, and all other portions of the state will continue to constitute a different region. If after applying these broader regions, a plan or issuer continues to have insufficient information to calculate the median of contracted rates, geographic regions will be based on Census divisions, with one region consisting of all MSAs in the Census division, and one region consisting of all other portions of the Census division. There are nine Census divisions, as published by the U.S. Census Bureau.⁵⁷ This approach will help to reduce instances in which a plan or issuer cannot rely on its own contracted rates to determine the QPA in cases where the plan or issuer is not limited to operating within a single state but instead has provider contracts in a multi-state region.

These interim final rules establish alternate geographic regions with respect to air ambulance services. Given the nature of air ambulance services, the infrequency with which they are provided relative to the other types of items and services subject to the No Surprises Act, and the lower prevalence of participating providers of air ambulance services, the Departments have

available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>. U.S. Census Bureau, Delineation Files, available at <https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html>.

⁵⁷ U.S. Department of Commerce Economics and Statistics Administration, U.S. Census Bureau, available at https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf.

determined not to apply a definition of geographic regions based on MSAs, as narrow regions would result in more instances of insufficient information.

Thus, for air ambulance services, a geographic region means one region consisting of all MSAs in the state, and one region consisting of all other portions of the state. If a plan or issuer does not have sufficient information to calculate the median of the contracted rates for an air ambulance service using that definition of a geographic region, these interim final rules apply broader regions based on Census divisions—that is, one region consisting of all MSAs in each Census division and one region consisting of all other portions of the Census division. Because air ambulance services can be furnished over large distances, these interim final rules provide that the geographic region to be applied for air ambulance services is determined based on the point of pick-up, meaning the location of the individual at the time the individual is placed on board the air ambulance. This approach is generally consistent with prevailing market practices among both private and public payers.

Non-Fee-for-Service Contractual Arrangements

The No Surprises Act provides that rulemaking to establish the methodology used to determine the QPA must take into account payments that are made by a plan or issuer that are not on a fee-for-service basis. The Departments are aware that many types of alternative reimbursement models exist that are not standard fee-for-service arrangements. For example, under a bundled payment arrangement, plans and issuers may reimburse a provider for multiple items and services under a single billing code. Other payers have capitation arrangements, under which a provider or panel of providers is paid a fixed amount per member per month.

The Departments understand that when a plan or issuer has a fully- or partially-capitated payment arrangement, the plan or issuer also typically has an internal methodology used to value claims for those payments made on a capitated basis. For example, a plan or issuer with capitation arrangements may have an underlying fee schedule that is used to calculate an individual's cost sharing. The Departments are of the view that, when a plan or issuer has an

underlying fee schedule used to determine cost sharing under non-fee-for-service contracts, it is reasonable for the plan or issuer to use the same methodology to assign a value to the item or service for purposes of determining the QPA. This approach is used by plans and issuers in other similar contexts, including when providing data for the risk adjustment program⁵⁸ and when making publicly available in-network rates under the transparency in coverage regulations.⁵⁹

Therefore, in the case of these alternative payment models, such as bundled and fully or partially capitated arrangements, where payment made by a plan or issuer is not fully on a fee-for-service basis, these interim final rules provide that the plan or issuer must calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items and services, if underlying fee schedule rates are available. The term “underlying fee schedule rate” means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant’s, beneficiary’s, or enrollee’s cost-sharing liability for the item or service, when that rate is different from the contracted rate.⁶⁰ If there is no underlying fee schedule rate for an item or service, these interim final rules provide that the plan or issuer must calculate the median contracted rate using a derived amount, which, consistent with the definition in the transparency in coverage regulations, is the price that a plan or issuer assigns an item or service for the purpose of internal accounting, reconciliation with providers, or for the purpose of submitting data in accordance with the requirements of 45 CFR 153.710(c).

The Departments considered alternative approaches to account for non-fee-for-service contractual arrangements, such as requiring plans and issuers to calculate median contracted

⁵⁸ See 45 CFR 153.710(c) (requiring an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a state in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business to derive the costs of all applicable provider encounters using its principal internal methodology for purposes of pricing those encounters).

⁵⁹ See 26 CFR 54.9815-2715A3(b)(1)(C); 29 CFR 2590.715-2715A3(b)(1)(C); 45 CFR 147.212(b)(1)(C) (requiring plans and issuers that use underlying fee schedule rates for calculating cost sharing to make publicly available on an internet website the underlying fee schedule rates for all covered items and services).

⁶⁰ This definition is substantially similar to the definition of “underlying fee schedule rate” in the transparency in coverage regulations at 26 CFR 54.9815-2715A1(a)(2)(xxii), 29 CFR 2590.715-2715A1(a)(2)(xxii), and 45 CFR 147.210(a)(2)(xxii).

rates for service bundles, or allowing plans or issuers to disregard certain types of non-fee-for-service contracts for purposes of calculating the median contracted rate. However, the approach specified in these interim final rules will ensure that the median contracted rate calculation accounts for a range of different contractual arrangements, including instances where a plan or issuer uses different types of contracting models with different providers and facilities. Using an underlying fee schedule or derived amount will allow plans or issuers to, in essence, convert each of their non-fee-for-service contracts into fee-for-service arrangements for purposes of calculating the median contracted rate. By avoiding instances where plans or issuers might have been required to disregard some of their contracts, this approach minimizes the number of instances in which a plan or issuer would not have sufficient information to calculate a median contracted rate and ensures that arrangements that pay for value over service volume are reflected in the QPA. In addition, this approach will result in the calculation of a QPA that aligns with a service code (or service-code modifier combination). The Departments anticipate this result will be helpful to nonparticipating providers and facilities in understanding how much cost sharing they are permitted to charge for a given item or service, and as they negotiate with the plan or issuer to determine the out-of-network rate.

It is the Departments' understanding that under certain capitated and bundled payment arrangements, providers' payments may be reconciled retrospectively to account for utilization, value adjustments, or other weighting factors that can affect the final payment to a provider. In addition, payers and providers may agree to certain incentive payments during the contracting process to promote the provision of higher-quality, lower-cost health care to participants, beneficiaries, or enrollees over time. These interim final rules specify that when calculating median contracted rates, plans and issuers must exclude risk sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments. The Departments are of the view that excluding these payments and payment adjustments from the median contracted rates used to determine cost sharing for items and services furnished by nonparticipating providers or

facilities is consistent with how cost sharing is typically calculated for in-network items and services, where the cost-sharing amount is customarily determined at or near the time an item or service is furnished, and is not subject to adjustment based on changes in the amount ultimately paid to the provider or facility as a result of any incentives or reconciliation process.

b. Indexing

The No Surprises Act provides that, in instances when the median contracted rate is determined as of January 31, 2019, the QPA for items and services furnished during 2022 is calculated by increasing the median contracted rate by the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI-U) over 2019, the percentage increase over 2020, and the percentage increase over 2021. The No Surprises Act further provides that the QPA for 2022 is then adjusted annually for items and services furnished during 2023 or a subsequent year. Therefore, the increase for any year is the CPI-U for the year, as so defined, divided by the CPI-U for the prior year. The combined percentage increase for 2019, 2020, and 2021 to determine the amount for 2022 is the product of the CPI-U increases for 2019, 2020, and 2021 multiplied together. For any year, the factor will be the quotient of CPI-U for the current year divided by the CPI-U for the prior year. For example, for an item or service provided in 2023, the 2023 QPA is the 2022 QPA multiplied by the $\text{CPI-U}_{2022} / \text{CPI-U}_{2021}$.

These interim final rules provide specifications for calculating the percentage increase in CPI-U to ensure that all plans and issuers adjust the percentage in a uniform manner. In order to ensure that uniformity, these interim final rules provide that plans and issuers will calculate the increases using the factors determined by the Treasury Department and the IRS, and published in guidance by the IRS. In determining the factors, these interim final rules provide that the percentage increase for any year is calculated by using the CPI-U published by the Bureau of Labor Statistics of the DOL. For this purpose, the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places. This allows the Departments to provide the percentage increase

factor before January 1 of each applicable year with sufficient time to adjust the QPAs for the year.

c. Special Rules for Unit-Based Services

These interim final rules provide special rules for calculating the QPA for items or services for which a plan or issuer generally determines the reimbursement level for the same or similar items or services by multiplying the contracted rate by another unit, such as time or mileage. In these cases, indexing the median contracted rate to calculate the QPA would result in an amount that does not reflect the other units that are generally considered when calculating the in-network payment amount. Therefore, when reimbursement levels are determined using this approach, these interim final rules specify that the QPA is calculated by determining the median contracted rate used for that item or service, indexing that median amount in accordance with the otherwise applicable rules regarding indexing, and then applying the pertinent multipliers. These interim final rules also include specific instructions for calculating the QPA for anesthesia services and for certain service codes for air ambulance services.

Anesthesia Services

Payers generally calculate payment amounts for anesthesia services by multiplying the negotiated rate for the anesthesia conversion factor that has been negotiated between the payer and the provider (expressed in dollars per unit) by (1) the base unit for the anesthesia service code, (2) the time unit, and (3) the physical status modifier unit. The base unit, time unit, and physical status modifier unit are specific to the individual receiving the anesthesia services. These units are not expressed in dollars per unit, nor do they vary by contract. The base units for an anesthesia service code are the American Society of Anesthesiologists Relative Value Guide base units for that service code. The time unit represents the length of time during which the anesthesia services were furnished, and for purposes of the QPA methodology, is measured in 15-minute increments or a fraction thereof. The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between the

various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

These interim final rules include a methodology for calculating the QPA for these anesthesiology services that reflects the manner in which providers are generally paid for these services. To calculate the QPA for anesthesia services furnished during 2022, these interim final rules require the plan or issuer to, first, take the median contracted rate for the anesthesia conversion factor (determined in accordance with the methodology for calculating median contracted rates for service code-modifier combinations) for the same or similar item or service as of January 31, 2019, and increase that amount to account for changes in the CPI-U, using the methodology described earlier in this section of the preamble. This amount is referred to as the indexed median contract rate. The plan or issuer must then multiply this indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit (using the value specified in the most recently published edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide), time unit, and physical status modifier units of the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the QPA.

To calculate the QPA for anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must use the indexed median contracted rate for the anesthesia conversion factor, and adjust that amount by the percentage increase in the CPI-U over the previous year using the methodology described earlier in this section of the preamble. The plan or issuer must then multiply that amount by the sum of the base unit (using the value specified in the most recently published edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide), time unit, and physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the QPA.

Air Ambulance Services

Payers often reimburse for air ambulance services in part by using air mileage service codes (A0435 and A0436) and reimbursement levels that reflect the number of miles an individual is transported by the air ambulance, which are referred to as loaded miles. Payment amounts are calculated by multiplying the negotiated rate for the service code, referred to in this rule as the air mileage rate, by the number of loaded miles. These interim final rules include a methodology for calculating the QPA for these air mileage service codes that reflects the manner in which providers are generally paid for the service codes.

To calculate the QPA for the portion of air ambulance services billed using the air mileage service codes that are furnished during 2022, the plan or issuer must first increase the median contracted rate, in accordance with 26 CFR 54.9816-6T(c)(1)(i), 29 CFR 2590.716-6(c)(1)(i), or 45 CFR 149.140(c)(1)(i), as applicable. This amount is referred to as the indexed median air mileage rate. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the QPA.

To calculate the QPA for air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must increase the indexed median air mileage rate, determined for such services furnished in the immediately preceding year, using the methodology described in 26 CFR 54.9816-6T(c)(1)(ii), 29 CFR 2590.716-6(c)(1)(ii), or 45 CFR 149.140(c)(1)(ii), as applicable. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the QPA.

d. Cases with Insufficient Information

Section 9816(a)(3)(E)(iii) of the Code, section 716(a)(3)(E)(iii) of ERISA, and section 2799A-1(a)(3)(E)(iii) of the PHS Act, as added by the No Surprises Act, specify an alternative process to determine the QPA in cases where a group health plan or health insurance issuer offering group or individual health insurance coverage lacks sufficient information to calculate

the median of contracted rates in 2019, as well as for newly covered items or services in the first coverage year after 2019.

Definition of Sufficient Information

Under these interim final rules, a plan or issuer is considered to have sufficient information to calculate the median of contracted rates if the plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with the methodology in these interim final rules. In the Departments' view, while a median contracted rate could be calculated with a smaller number of contracts, requiring a minimum of three contracted rates is supported by the statute's direction to calculate a median, rather than a mean. Furthermore, the Departments have determined that three contracted rates for a particular item or service in a geographic region represents the minimum number of contracts necessary to reasonably reflect typical market negotiations while reducing the potential for outlier rates to unduly influence the calculation of the QPA.

Under section 9816(a)(3)(E)(iii) of the Code, section 716(a)(3)(E)(iii) of ERISA, section 2799A-1(a)(3)(E)(iii) of the PHS Act, and these interim final rules, where a plan or issuer that initially does not have sufficient information to calculate the median contracted rate based on January 31, 2019 contracted rates (or for new plans and coverage or new service codes, as discussed in more detail in this section of the preamble) later gains sufficient information, the plan or issuer must calculate the QPA using the median contracted rate for the first sufficient information year. The first sufficient information year is defined as: (1) in the case of an item or service for which a plan or issuer does not have sufficient information to calculate the median of contracted rates in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of contracted rates in the year immediately preceding that first year after 2022; and (2) in the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the

plan or issuer has sufficient information to calculate the median of the contracted rates in the year immediately preceding that first year.

In cases in which contracted rates for a year after 2019 must be used to calculate the median contracted rate, a plan or issuer will be considered to have sufficient information to calculate the median contracted rate for a year if, with respect to that year, both of the following conditions are met: (1) the plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with the methodology in these interim final rules; and (2) the contracted rates account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or of the administering entity, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

The requirement that a plan or issuer have at least three contracted rates for a particular item or service in a geographic region is the same as the requirement that applies when determining whether there is sufficient information to calculate a median contracted rate for items and services furnished during 2022 using the median of contracted rates as of January 31, 2019. The 25 percent minimum claims volume requirement, however, applies where only contracted rates for years after 2019 are used to determine whether a plan or issuer has sufficient information to calculate the median contracted rate in the first sufficient information year. While the Departments are not concerned about manipulation of the QPA in the majority of cases where the median contracted rate is based on 2019 contracted rates, the Departments recognize the potential for plans and issuers to engage in selective contracting practices that artificially change the median contracted rate in cases where subsequent year contracted rates are used to determine the QPA. Therefore, this requirement will help to ensure that when contracted rates for years after 2019 are used to calculate a median contracted rate, those network contracts

represent a reasonable proportion of a plan's or issuer's total claims and are not designed to manipulate the QPA.

Eligible Databases

In cases in which a plan or issuer does not have "sufficient information" to calculate a median contracted rate, the No Surprises Act directs the plan or issuer to determine the QPA through use of any database that is determined, in accordance with rulemaking issued by the Departments, to not have any conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility for relevant services furnished in the applicable geographic region (such as a state all-payer claims database).

These interim final rules establish standards for databases, referred to as eligible databases, that may be used to determine the QPA. State all-payer claims databases are categorically eligible under these interim final rules because they are specifically identified as not having any conflicts of interest and as having sufficient information reflecting allowed amounts in section 9816(a)(3)(E)(iii)(I) of the Code, section 716(a)(3)(E)(iii)(I) of ERISA, and section 2799-1(a)(3)(E)(iii)(I) of the PHS Act. Other third-party databases may also be eligible, provided all of the following conditions are satisfied.

First, the database or the organization maintaining the database cannot be affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services, or any member of the same controlled group as, or under common control with, any such entity. For example, if a majority of the members on the governing board of a database or the organization maintaining the database are associated with a health insurance issuer, the database would be considered to have a conflict of interest under these interim final rules, since it is controlled by the issuer. As another example, if an issuer owns 40 percent of the stock of the organization that maintains a database, and its subsidiary owns an additional 20 percent of the stock of the organization that maintains the database, the database would be considered to have a conflict of interest under these interim final rules, since

it is effectively controlled by the issuer. As a third example, if an issuer and the organization that maintains a database are both subsidiaries of the same parent organization, the database would be considered to have a conflict of interest under these interim final rules, since it is affiliated with the issuer. In the Departments' view, this standard is critical to ensuring the independence of any database used to determine the QPA. The Departments solicit comment on whether a database should not be affiliated with, or owned or controlled by, other entities, such as plan sponsors or third-party administrators, in order to avoid a conflict of interest. The Departments also seek comment on whether to establish a specific threshold that a party's minority ownership interest must meet or exceed in order to create a conflict of interest for purposes of these interim final rules.

For purposes of applying the controlled group rules to eligible databases, a controlled group means a group of two or more persons that is treated as a single employer under Code sections 52(a), 52(b), 414(m), or 414(o). The Treasury Department and the IRS are considering whether further guidance is needed under section 52(a) or (b) of the Code to address either organizations exempt from tax under section 501(a) of the Code or nonprofit organizations that, although not exempt from tax under section 501(a) of the Code, do not have members or shareholders that are entitled to receive distributions of the organization's income or assets (including upon dissolution) or that otherwise retain equity interests similar to those generally held by owners of for-profit entities. Until further guidance is issued, those two types of organizations may either rely on a reasonable, good-faith application of section 52(a) and (b) of the Code (taking into account the reasons for which the controlled group rules are incorporated into the definition of eligible database) or apply the rules set forth in 26 CFR 1.414(c)-5(a) through (d) (but substituting "more than 50 percent" in place of "at least 80 percent" each place it appears in 26 CFR 1.414(c)-5).

Second, the database must have sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health

insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region. The Departments recognize that for a database to be used to calculate the QPA, the database should contain sufficient data to reflect the true market dynamics in a given geographic region. However, in order to provide flexibility in the initial implementation of the No Surprises Act, these interim final rules do not establish a specific definition of when a database is considered to have sufficient information. The Departments seek comment on how to define when a database has sufficient information, including whether to establish specific criteria that a claims database would need to satisfy in order to demonstrate that it has sufficient information reflecting in-network payment amounts for providers or facilities in the applicable geographic region, such as a requirement that the database represents a specified minimum percentage of the claims volume for the region.

Third, the database must have the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act),⁶¹ and the Children’s Health Insurance Program under title XXI of the Social Security Act.

To calculate the QPA for an item or service furnished during 2022 (or in the case of newly covered items or services, in the first coverage year) using an eligible database, the plan or issuer must first identify the rate in the database that is equal to the median of the in-network

⁶¹ Under section 1115 of the Social Security Act, the Secretary of HHS has the authority to approve experimental, pilot, or demonstration projects that, in his judgment, are likely to assist in promoting the objectives of the Medicaid statute. Under section 1115 authority, the Secretary may waive compliance with certain provisions of Medicaid and CHIP law and may authorize federal matching funds for state expenditures that would not otherwise be federally matchable under the Medicaid and CHIP statutes. Many states have section 1115 demonstrations under which they cover services that would not otherwise be covered under the Medicaid or CHIP programs.

allowed amounts for the same or similar item or service in the geographic region in the year immediately preceding the year in which the item or service is furnished (or in the case of a newly covered item or service, the year immediately preceding the first coverage year). It is the Departments' view that in-network allowed amounts for items and services are a reasonable proxy for contracted rates, and that where there is insufficient information to calculate the QPA based on the median of a plan's or issuer's own contracted rates, using the median of in-network allowed amounts for all private payers in an eligible database is a reasonable method for approximating the median contracted rate for items and services in the applicable geographic region. The Departments are also of the view that determining the QPA for an item or service using the median of in-network allowed amounts for the same or similar item or service in the geographic region in the year immediately preceding the year in which the item or service is furnished is reasonably likely to result in levels of cost sharing that are generally in line with the cost-sharing liability incurred by participants, beneficiaries, and enrollees in plans with similar levels of in-network cost-sharing for the same or similar items or services.

Once the median in-network allowed amount has been identified, that rate is then increased by the percentage increase in the CPI-U over the previous year using the methodology described earlier in this section of the preamble. For each subsequent year before the first sufficient information year, the plan or issuer must increase the QPA applicable to items or services furnished in the immediately preceding year by the percentage increase in CPI-U over the preceding year. Plans and issuers must continue to use this methodology until the first sufficient information year, at which point the plan or issuer must calculate the median contracted rate and determine the QPA using the standard methodology discussed earlier in this section of the preamble.

These interim final rules require that plans and issuers use a consistent methodology when relying on an eligible database. Specifically, for any particular item or service, a plan or issuer using a database must use the same database to determine the QPA for that item or service

through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).⁶² This consistency requirement is designed to ensure that when relying on an eligible database to determine the QPA for an item or service, a plan or issuer cannot vary the database selected due to the rates associated with that item or service. The Departments seek comment on this consistency requirement and whether additional standards or guidance are needed to ensure compliance and prevent abuse.

Finally, these interim final rules codify section 9816(d) of Code, section 716(d) of ERISA, and section 2799A-1(d) of PHS Act, as added by the No Surprises Act, which provide that a plan or issuer that uses an eligible database to determine the QPA by reason of having insufficient information is responsible for any costs associated with accessing such database. The Departments solicit comment on ways to help ensure that plans and issuers are charged only reasonable costs for accessing such databases and that entities that provide eligible databases are transparent about their fees and fee structures associated with this process.

New Plans and Coverage

The No Surprises Act directs the Departments to establish a methodology for the sponsor of a group health plan or a health insurance issuer that did not offer any plan or coverage in a geographic region in 2019 to determine QPAs for the first year in which the plan or coverage will be offered in the geographic region. For each subsequent year, that amount is increased by the percentage increase in the consumer price index for all urban consumers over the previous year.

The Departments recognize that while a sponsor or issuer may be newly offering coverage in a geographic region, the sponsor or issuer may have sufficient existing provider

⁶² For example, these interim final rules permit a plan or issuer to rely on different state all-payer claims databases, based on the geographic region in which an item or service is furnished, as state all-payer claims databases may not have sufficient data for items and service furnished outside of the state.

contracts under other current coverage in the geographic region where an item or service is furnished to calculate the QPA. The Departments clarify that it is not necessary to establish special procedures to calculate the QPA in these situations. Therefore, under these interim final rules, if the plan or issuer newly offering coverage in a geographic region for a year after 2019 otherwise has sufficient information to calculate a median contracted rate in 2019 in the geographic region where the item or service is furnished, the QPA is determined using the standard methodology for calculating median contracted rates discussed earlier in this section of the preamble.

The Departments recognize that the standard methodology would not be available, however, in cases where the plan or issuer does not have sufficient information to calculate a median contracted rate in the geographic region in which the item or service is furnished, such as in situations where the sponsor or issuer did not offer any plan or coverage in 2019. In this case, the plan or issuer must determine the QPA in accordance with the rules applicable to plans or issuers with insufficient information, or for newly covered items and services, including the use of an eligible database, as discussed earlier in this section of the preamble.

For each subsequent year the plan or coverage is offered in the geographic region, the plan or issuer must increase the QPA for items or services furnished in the immediately preceding year by the percentage increase in the CPI-U over the previous year to determine the QPA for items and services furnished in that year. Under this approach, new plans and coverage that initially do not have sufficient information to calculate a median contracted rate must use a QPA based on information for the first year of coverage from an eligible database indefinitely, updated only by the inflation adjustment. The Departments seek comment on whether the methodology should instead allow new plans and coverage to transition to calculating a QPA using median contracted rates in an applicable first sufficient information year.

New Service Codes

When service codes are created, plans and issuers may be unable to calculate the QPA using the approaches discussed earlier, because neither the plan or issuer nor any eligible databases have sufficient information regarding the new service code. This situation may occur for new service codes when the service codes describe items or services that have not previously been widely furnished. This situation may also occur when service codes are substantially revised, resulting in new service codes or new descriptors for existing service codes that substantially alter the types of services that would be billed using the original service codes. In this case, the plan, issuer, or eligible database may have sufficient information regarding rates for items and services billed under the service code prior to the revision, but that information may no longer reflect the rates associated with the items and services billed under the revised service code. The No Surprises Act does not specify a methodology for calculating the QPA in these circumstances. However, in the Departments' view, it is necessary that these interim final rules establish a methodology that plans and issuers can rely on for calculating QPAs for new service codes during periods of time when no eligible databases would reasonably be expected to have sufficient data to calculate a QPA.

These interim final rules define "new service code" to mean a service code that was created or substantially revised in a year after 2019. In situations in which a plan or issuer is billed for a covered item or service using a new service code, the plan or issuer must first identify a reasonably related service code that existed in the immediately preceding year. For example, a reasonably related service code might be another service code within the same family of codes, or might involve services that represent similar relative value units. This related service code will be used as a benchmark for determining the QPA for the new service code. The Departments seek comment on whether additional rules are needed regarding how plans and issuers should be required to identify a reasonably related service code, and on whether the Departments should develop a crosswalk methodology to identify related service codes for each new service code.

The Departments are of the view that, although Medicare payment rates may differ substantially from rates paid by plans and issuers, it is reasonable to use Medicare payment rates to approximate the relative cost of two different but reasonably related service codes. Therefore, if CMS has established a payment rate under the Medicare program for an item or service billed under the new service code, the plan or issuer must calculate the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service under the related service code (with both rates disregarding any adjustments for value-based purchasing arrangements that could lead to bonuses or deductions), and multiply that ratio by the QPA for the related service code for the year in which the item or service is furnished.

The Departments recognize that in some cases the Medicare program might not immediately establish a payment rate for items and services billed under a new service code. Therefore, these interim final rules establish a secondary approach to determine the QPA in these situations. Specifically, for items and services billed using a new service code for which Medicare has not established a payment rate, the plan or issuer must calculate the QPA by first calculating the ratio of the rate that the plan or issuer reimburses for an item or service billed under the new service code compared to the rate that the plan or issuer reimburses for an item or service under the related service code (the relativity ratio), and then multiplying the relativity ratio by the QPA for the item or service billed under the related service code. These interim final rules do not specify a particular method that plans and issuers must use to calculate this relativity ratio. However, the Departments expect plans and issuers to use a reasonable method for making the calculation, and seek comment on whether future rulemaking should specify additional requirements for determining the relativity ratio. For example, plans and issuers could be required to calculate the ratio using the medians or means of the contracted rates for each of the two services. However, the Departments recognize that it may take time for plans and issuers to enter into negotiated rates for new service codes, and therefore the medians or means may

change over time. Alternatively, plans and issuers could be required to calculate the relativity ratio using rates from one contract, based on the assumption that negotiated rates within any given contract would generally produce a similar relativity ratio. The Departments are of the view that using rates from two different contracts would not constitute a reasonable method for calculating the relativity ratio, as this approach could introduce into the relativity ratio, variation from factors that are unrelated to the relative cost of furnishing the item or service, such as the negotiating power of the parties to the contract.

Under the methodology in these interim final rules, for items or services furnished in any subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information in the immediately preceding year), the plan or issuer must calculate the QPA by increasing the QPA calculated for the prior year by the percentage increase in CPI-U over the immediately preceding year.

However, for an item or service billed using a new service code, and furnished in the first sufficient information year for such item or service with respect to such plan or coverage, or furnished in the first year for which an eligible database has sufficient information to enable the plan or issuer to calculate the QPA using the processes that generally apply when an issuer or plan has insufficient information, the plan or issuer must calculate the QPA in accordance with 26 CFR 54.9816-6T(c)(3), 29 CFR 2590.716-6(c)(3), or 45 CFR 149.140(c)(3), as applicable. Thus, once the plan or issuer or an eligible database has sufficient information to calculate a QPA, the QPA for a new service code would be calculated using the median contracted rate of the plan or issuer, or the median of the in-network allowed amounts in the eligible database.

The Departments seek comment on any alternate approaches that could be used to determine the QPA for new service codes.

e. Information to be Shared about the QPA

The No Surprises Act directs the Departments to specify the information that a plan or issuer must share with a nonparticipating provider or nonparticipating emergency facility, as applicable, when making a determination of a QPA.

The Departments recognize that providers, emergency facilities, and air ambulance providers subject to the surprise billing rules need transparency regarding how the QPA was determined. This information is also important in informing the negotiation process. In addition, IDR entities are directed by statute to consider the QPA when selecting an offer submitted by the parties through the IDR process. Therefore, to decide whether to initiate the IDR process and what offer to submit, a provider, emergency facility, or provider of air ambulance services must know not only the value of the QPA, but also certain information on how it was calculated.

The Departments seek to ensure transparent and meaningful disclosure about the calculation of the QPA while minimizing administrative burdens on plans and issuers. These interim final rules therefore require that plans and issuers make certain disclosures with each initial payment or notice of denial of payment, and that plans and issuers must provide additional information upon request of the provider or facility. This information must be provided in writing, either on paper or electronically, to a nonparticipating provider, emergency facility, or provider of air ambulance services, as applicable, when the QPA serves as the recognized amount.

First, a plan or issuer must provide the QPA for each item or service involved.

Second, a plan or issuer must provide a statement certifying that, based on the determination of the plan or issuer: (1) the QPA applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and (2) each QPA shared with the provider or facility was determined in compliance with the methodology outlined in these interim final rules. These interim final rules require a statement from the plan or issuer that the QPA applies for purposes of the recognized amount so that providers and facilities will understand that the plan or issuer has determined that

neither an All-Payer Model Agreement nor a specified state law applies for purposes of calculating a participant's, beneficiary's, or enrollee's cost-sharing liability, but rather that cost-sharing liability has been calculated using the QPA. With respect to air ambulance services, the statement will ensure providers of air ambulance services understand that the QPA, rather than the billed charge, applies for purposes of calculating the cost-sharing liability, because the plan or issuer has determined that the QPA is lower than the billed charge. The Departments expect that in most if not all cases where the QPA serves as the basis for determining the recognized amount, the federal IDR process will govern any dispute over payment instead of a specified state law or process. Therefore, this notice will also serve to direct providers or facilities to the federal IDR process if the parties cannot agree on an out-of-network rate.

Third, a plan or issuer must provide a statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day open negotiation period does not result in a determination, generally, the provider or facility may initiate the IDR process within 4 days after the end of the open negotiation period. The plan or issuer must also provide contact information, including a telephone number and email address, for the appropriate office or person to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

In addition, upon request of the provider or facility, a plan or issuer must provide, in a timely manner, information about whether the QPA includes contracted rates that were not set on a fee-for-service basis for the specific items and services at issue and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount. If a related service code was used to determine the QPA for a new service code, a plan or issuer must provide information to identify which related service code was used. Similarly, if an eligible

database was used to determine the QPA, a plan or issuer must provide information to identify which database was used to determine the QPA.

Finally, if applicable upon request, a plan or issuer must provide a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded for purposes of calculating the QPA. Having information about whether the median contracted rate excludes these types of payment adjustments will better inform the open negotiation and IDR process.

The Departments seek comment on these disclosure requirements and on what additional information a plan or issuer should be required to share with a provider or facility about the QPA, either in all cases or upon request. The Departments also seek comment on whether a specific definition or standard is needed to ensure that information provided upon request is disclosed in a timely manner.

f. Audits

The No Surprises Act requires rulemaking to establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the No Surprises Act with respect to the year involved.⁶³

The enforcement responsibilities of HHS and the states with respect to oversight of health insurance issuer compliance with the federal insurance market reforms are set forth in the PHS Act. Pursuant to section 2723(a)(1) of the PHS Act, as amended by the No Surprises Act, states have primary enforcement authority over health insurance issuers regarding the provisions of Parts A and D of title XXVII of the PHS Act. Under this framework, HHS has enforcement

⁶³ See section 9816(a)(2)(A) of the Code; section 2799A-1(a)(2)(A) of the PHS Act. The DOL and OPM will rely on the existing agency processes to ensure compliance with the No Surprises Act, as discussed in this section of the preamble.

authority over issuers in a state if the Secretary of HHS makes a determination that the state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act.⁶⁴

DOL and the Treasury Department generally have primary enforcement authority over private sector employment-based group health plans. The IRS has jurisdiction over certain church plans. HHS also has primary enforcement authority over non-federal governmental plans, such as those sponsored by state and local government employers.⁶⁵ OPM has jurisdiction over FEHB plans, which are federal governmental plans.

The Departments will generally use existing processes to ensure compliance with Code, ERISA, and PHS Act requirements that apply to group health plans and health insurance issuers, including the provisions added by the No Surprises Act. HHS's enforcement procedures related to the PHS Act federal insurance market reforms are set forth in section 2723 of the PHS Act and 45 CFR 150.101 *et seq.*, including bases for initiating investigations and performing market conduct examinations. Section 504 of ERISA provides DOL with authority to determine whether any person has violated or is about to violate any provision of ERISA or any regulation or order thereunder. The interim final rules include an audit provision establishing that HHS's existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA consistent with these interim final rules. HHS intends to amend its enforcement regulations through future notice and comment rulemaking to reflect the amendments made to the PHS Act by the No Surprises Act. OPM will audit FEHB plans to ensure that such plans are in compliance with the requirement of determining and applying a QPA.

- vii. Determination of Out-of-Network Rate in the Absence of a Specified State Law or an Applicable All-Payer Model Agreement

⁶⁴ Section 2723(a)(2) and (b)(1)(A) of the PHS Act. *See also* 45 CFR 150.203.

⁶⁵ See section 2723(b)(1)(B) of the PHS Act.

In instances in which a specified state law or All-Payer Model Agreement does not apply for purposes of specifying the out-of-network rate, the out-of-network rate is determined either through agreement between the provider or facility and plan or issuer; or through an IDR process, if agreement cannot be reached and such process is initiated. If the parties agree to an amount of payment prior to the date on which a certified IDR entity makes a determination with respect to such items or services, that agreed upon amount is the out-of-network rate. Otherwise, the out-of-network rate is the amount of payment determined by the certified IDR entity for the items or services.⁶⁶

3. Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing a Notice of Denial

The No Surprises Act and these interim final rules establish several procedural requirements that apply to group health plans and health insurance issuers to ensure that billing disputes related to items and services subject to the balance billing protections in the No Surprises Act are resolved in a timely fashion. These include timeframes for: a plan or issuer to send a notice of denial of payment or make an initial payment; the length of any open negotiation period regarding payment; and initiating the IDR process following an open negotiation period. However, those three requirements do not apply under certain circumstances with regard to post-stabilization services or to out-of-network non-emergency services (other than out-of-network air ambulance services) if the provider or facility provided notice to, and received consent from, the participant, beneficiary, or enrollee (or their authorized representative), as discussed later in this preamble.

Therefore, it is critical that a group health plan or health insurance issuer have knowledge of any notice provided and consent given under these interim final rules for items and services that it covers, and that would otherwise be subject to the surprise billing provisions in the statute and these interim final rules. As discussed later in this preamble, the interim final rules issued by

⁶⁶ As noted previously, the Departments intend to implement the federal IDR process in future rulemaking.

HHS in this rulemaking require providers and facilities to notify plans and issuers when the notice and consent criteria have been satisfied. Absent receiving this information, a plan or issuer must assume that the individual has not waived the protections provided in these interim final rules, and must therefore calculate cost sharing, apply cost sharing to deductibles and out-of-pocket limits, and make any payments to providers and facilities before an individual has satisfied the coverage deductible, accordingly. In instances where a plan or issuer does receive this information, it may rely on the provider's or facility's representation as being true and accurate, unless and until the plan or issuer knows or reasonably should know otherwise. Thus, if a provider or facility indicates to a plan or issuer that the notice and consent described in these interim final rules was properly and timely given and received, the plan or issuer may rely on that information and, for example, apply out-of-network cost sharing for the applicable items and services, unless and until the plan or issuer knows or reasonably should know that the notice and consent was not properly and timely given and received. In cases where a plan or issuer believes that notice was not properly and timely given and received, notwithstanding a provider's or facility's assertion to the contrary, the plan or issuer should apply the cost-sharing and other requirements set forth in these interim final rules and applicable state law by, among other actions, reprocessing any claims that were not processed consistently with those requirements. The plan or issuer may also submit a complaint against the provider or facility as set forth in these interim final rules at 45 CFR 149.450.

Sections 9816(a)(1)(iv)(I) and 9817(a)(3)(A) of the Code, sections 716(a)(1)(iv)(I) and 717(a)(3)(A) of ERISA, sections 2799A-1(a)(1)(iv)(I) and 2799A-2(a)(3)(A) of the PHS Act, and these interim final rules, require plans and issuers to send "an initial payment or notice of denial of payment" not later than 30 calendar days after a nonparticipating provider or facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections for emergency services, non-emergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by

nonparticipating providers of air ambulance services. Given that plans and issuers cannot comply with this requirement unless the plan or issuer first determines that the billed items and services are covered under the plan or coverage, these interim final rules require that the plan or issuer make such determination not later than 30 calendar days after a nonparticipating provider or facility submits a bill related to the items and services that fall within the scope of the new surprise billing protections for emergency services, non-emergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services.

The Departments specify in these interim final rules that the 30-calendar-day period generally begins on the date the plan or issuer receives the information necessary to decide a claim for payment for such services, commonly known as a “clean claim” under many existing state laws. To the extent feasible, the Departments encourage providers and facilities to include information about whether the surprise billing protections apply to an item or service on the claim form itself. With respect to non-emergency services, HHS requires, under 45 CFR 149.420(i), nonparticipating providers (or the participating facility on behalf of the nonparticipating provider) to timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility. In addition, in all cases, under either 45 CFR 149.410(e) or 45 CFR 149.420(i), providers and facilities must notify the plan or issuer as to whether the requirements for notice and consent have been met when transmitting the bill, either on the bill or in a separate document. The Departments seek comments with recommendations on how HIPAA standard transactions to submit claims could be modified to accommodate the submission of several types of information on the claim itself. Specifically, the Departments seek comment on how HIPAA standard transactions to submit claims could be modified to include whether the surprise billing protections apply to the items and services included on a claim, whether the item or service was furnished during a visit at a participating health care facility, and whether the requirements for notice and consent have been met. The 30-

calendar-day initial payment period also does not prohibit payments outside of the 30-calendar-day timeframe for any future adjustments for errors in payment, such as in cases of duplicate bills where providers and plans or issuers reconcile overpayments. The Departments expect that plans and issuers will act reasonably and in good faith when requesting additional information, by providing specific detail to help ensure that the claimant, provider, or facility understands what is required to perfect the claim. The Departments may specify additional standards if the Departments become aware of instances of abuse and gaming where plans and issuers are unduly delaying making an initial payment or sending a notice of denial to providers on the basis that the provider has not submitted a clean claim. The Departments solicit comment on whether any additional standards are necessary to prevent abusive claims payment practices. Under these interim final rules, a notice of denial of payment means, with respect to an item or service for which benefits are subject to the surprise billing protections, a written notice from the plan or issuer to the provider or facility that payment for the item or service will not be made by the plan or coverage and which explains the reason for denial. A notice of denial of payment could be provided, for example, if the item or service is covered but is subject to a deductible greater than the recognized amount.

In the Departments' view, the statute's reference to an "initial" payment does not refer to a first installment. Rather, this initial payment should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage, prior to the beginning of any open negotiations or initiation of the IDR process. In cases where the provider or facility is willing to accept the cost-sharing amount plus the initial payment (or the cost-sharing amount alone, in cases where a denial of payment is sent) as payment in full, this amount will be treated as the out-of-network rate. If plans and issuers make initial payments that providers and facilities are willing to accept (when combined with the cost-sharing amount) as payment in full, the administrative costs of

determining the out-of-network amount will be significantly reduced through the avoidance of an open negotiation period and IDR process.

These interim final rules do not require plans and issuers, when making an initial payment to providers or facilities, to make any specific amount of minimum initial payment. However, several state balance billing laws set standards for minimum initial payment amounts. For example, in Washington State, issuers are required to pay an out-of-network provider or facility a commercially reasonable amount, reduced by the applicable cost-sharing amount, within 30 calendar days of receipt of a claim to which the state's balance billing protections apply. Requiring a minimum initial payment amount may help reduce the number of cases that go to arbitration in some states, and could help to reduce the number of cases that go to the federal IDR process established under the No Surprises Act.

The Departments seek comment on whether to set a minimum payment rate or methodology for a minimum initial payment in future rulemaking, and if so, what that rate or methodology should be. For example, a minimum payment rate could be a specific percentage of the Medicare rate, a specific percentage of the plan or issuer's QPA for the item or service, an amount calculated in the same way the plan or issuer typically calculates payment for the specific item or service to nonparticipating providers or facilities, an amount representing the highest amount that would result from applying two or more of these or other methodologies, or any other method. To the extent comments suggest that a percentage of a rate calculated or determined in a specific way would be appropriate, the Departments seek comment regarding an appropriate specific percentage. The Departments also seek comment on whether a minimum payment rate should be defined as a commercially reasonable rate based on payments for the same or similar services in a similar area, without requiring any specific methodology. In addition, the Departments seek comment regarding the impact of these provisions on underserved and rural communities, and other communities facing a shortage of providers.

The Departments are aware that the timeframes for deciding post-service claims under the claims and appeals rules issued under section 2719 of the PHS Act and the timeframes for sending an initial payment or notice of denial of payment under these final rules may not always align. The Departments seek to minimize confusion about which types of disputes should be resolved through a plan or issuer's internal claims and appeals process instead of the IDR process established by the No Surprises Act.

The ERISA claims procedure regulation requires group health plans to notify a claimant of a benefit determination for post-service claims not later than 30 days after receipt of the claim. A plan can generally extend this period once for up to 15 days for matters beyond the control of the plan, including if the claimant fails to provide information necessary to decide the claim. In such cases, the plan may notify the claimant they provided insufficient information within 30 days, and the plan must give the claimant at least 45 days to provide additional information. After the information is provided, the plan has 15 days to make a determination. Claims that result in an adverse benefit determination (ABD) may be appealed within 180 days following receipt of the notice of the ABD. The requirements of the ERISA claims procedure regulation are incorporated by reference in the internal claims and appeals and external review requirements added by the Affordable Care Act to section 2719 of the PHS Act and, therefore, subject to limited exceptions, apply to all non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets.

If an initial claim submitted is a clean claim, the timeframes for making the relevant determinations would generally be aligned under these interim final rules and the ERISA claims procedure regulation. However, if a claim is submitted without sufficient information to make a benefit determination, under the ERISA claims procedure regulation, the plan would only have 15 days to make a determination once the claim is resubmitted with the additional information. Yet, under the No Surprises Act and these interim final rules, the plan would have up to 30 calendar days to send a notice of denial of payment or an initial payment to the out-of-network

provider from the time the claim is resubmitted with additional information. Consistent with the requirement that plans and issuers provide an initial payment or notice of denial of payment within 30 calendar days of a provider or facility submitting a clean claim, the Departments clarify that while the ERISA claims procedure regulation would require plans to make a benefit determination within 15 days of a claim being resubmitted with additional information, plans and issuers have 30 calendar days (which is an additional 15 days) to make an initial payment to a nonparticipating provider or facility, or send a separate notice of denial of payment.

The Departments note that there is also a significant distinction between an ABD, which may be disputed through a plan's or issuer's claims and appeals process, and a denial of payment or an initial payment that is less than the billed amount under these interim final rules, which may be disputed through the open negotiation process or through the IDR process. In general, when adjudication of a claim results in a participant, beneficiary, or enrollee being personally liable for payment to a provider or facility, this determination may be an ABD that can be disputed through a plan's or issuer's claims and appeals process. Conversely, when: (1) the adjudication of a claim results in a decision that does not affect the amount the participant, beneficiary, or enrollee owes; (2) the dispute only involves payment amounts due from the plan to the provider; and (3) the provider has no recourse against the participant, beneficiary, or enrollee, the decision is not an ABD and the payment dispute may be resolved through the open negotiation or the IDR process. This clarification is consistent with previous guidance included in FAQs related to the ERISA claims procedure regulation, which have explained that with respect to in-network benefits, the regulation does not apply to requests by health care providers for payments due to the provider, rather than due to the claimant, where the provider has no recourse against the claimant for amounts, in whole or in part, not paid by the plan.⁶⁷ The Departments acknowledge that there may be instances where a participant, beneficiary, or

⁶⁷ See Benefit Claims Procedure Regulation FAQs, Q A-8, available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/benefit-claims-procedure-regulation>; see also Q C-12 (clarifying that failure to make payment in whole or in part due to the imposition of cost-sharing requirements is an ABD).

enrollee appeals an ABD (such as, a determination of cost-sharing amounts) through the claims and appeals process concurrently with a provider's challenge to a payment amount through the IDR process.

4. Surprise Billing Complaints Regarding Group Health Plans and Health Insurance Issuers

Section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and section 2799A-1(a)(2)(B)(iv) of the PHS Act direct the Departments to establish a process to receive complaints regarding violations of the application of QPA requirements by group health plans and health insurance issuers offering group or individual health coverage. The Departments are of the view that, in order to effectively enforce the No Surprises Act balance billing protections, the complaints process should extend to all of the consumer protection and balance billing requirements as described in these interim final rules that apply to group health plans and health insurance issuers offering group or individual health coverage. As such, these interim final rules establish a process by which the Departments will receive complaints regarding violations by plans and issuers of the requirements under sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A-1 and 2799A-2 of the PHS Act. The Departments seek comment on whether the complaints process should be restricted to the QPA or extended as described in these interim final rules.

The No Surprises Act also adds section 2799B-4(b)(3) of the PHS Act, which directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding balance billing requirements under sections 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the PHS Act and to respond to such complaints within 60 days. As such, HHS is issuing HHS-only interim final rules to establish a process by which HHS will receive complaints regarding violations of these requirements by health care providers, facilities, and providers of air ambulance services.

For purposes of the complaint processes for plans and issuers, providers, facilities, and providers of air ambulance services, these interim final rules define a complaint as a written or

oral communication that indicates there has been a potential violation by a plan or issuer of sections 9816 or 9817 of the Code, sections 716 or 717 of ERISA, or sections 2799A-1, 2799A-2 of the PHS Act, or a potential violation by a provider, facility, or provider of air ambulance services of sections 2799B-1, 2799B-2, 2799B-3 and 2799B-5 of the PHS Act, whether or not a violation actually occurred. A complainant means any individual, or their authorized representative, who files a complaint as defined in these interim final rules.

The Departments seek to minimize the burden of filing a complaint and seek to require only the information necessary to process the complaint and conduct an investigation if deemed necessary. Therefore, these interim final rules specify that the Departments will consider a complaint to be filed on the date on which the Departments receive an oral or written statement with information about the complaint sufficient to identify the parties involved (including the plan sponsor, if the complaint involves a group health plan), and the action or inaction that is the subject of the complaint. The information may also include the timing of the alleged violation, and the state where the alleged violation occurred. The Departments seek comment on the information needed to file a complaint, and the definitions in this section.

The Departments have considered whether a complaint should be filed within a defined amount of time of the alleged violation. The Departments understand that timely action is necessary to investigate and adjudicate billing matters and therefore considered whether complainants should be required to file a complaint regarding an alleged violation of the requirements in these interim final rules by a plan, issuer, health care provider or provider of air ambulance services within 90 or 180 calendar days after learning of the alleged violation. Without a time requirement for filing a complaint, the Departments may be restricted in directing the complainant to other state or federal resolution processes with timing requirements such as the internal and external claims review process as described in section 2719 of the PHS Act, or an appropriate IDR process as defined in sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A-1 and 2799A-2 of the PHS Act. However, the Departments

are of the view that every complaint should be processed and investigated as appropriate to ensure that any necessary enforcement action can be taken. Therefore, these interim final rules do not include a time period upon which a complaint must be filed. The Departments seek comment on whether a complainant should be required to file a complaint within a given time period and if so within what time period a complaint should be filed for the purpose of this section.

Section 2799B-4 of the PHS Act directs HHS to respond to complaints regarding violations of balance billing protections by health care providers, facilities, and providers of air ambulance services within 60 days of receipt. The Departments are of the view that the timing for responding to complaints regarding plans and issuers should be the same as that for providers to ensure timely resolution. Therefore, upon receiving the information necessary to file a complaint regarding a plan or issuer, the Departments will respond to complainants under section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and section 2799A-1(a)(2)(B)(iv) of the PHS Act no later than 60 business days after the complaint is received. Similarly, HHS will respond to a processed complaint regarding a health care provider, facility, or provider of air ambulance services under section 2799B-4 of the PHS Act no later than 60 business days after the complaint is received.

The response will be by oral or written means, and will acknowledge receipt of the complaint, notify the complainant of their rights and obligations under the complaints process, and describe the next steps of the complaint resolution process. The Departments may also request any additional information needed to process the complaint. The requested information may include an explanation of benefits, processed claims, information about the health care provider, facility, or air ambulance service involved; information about the plan or issuer covering the individual; information to support a determination regarding whether the service was an emergency service or non-emergency service; the summary plan description, policy, certificate, contract of insurance, membership booklet, outline of coverage or other evidence of

coverage the plan or issuer provides to their participant, beneficiary, or enrollee; documents regarding asserted facts in the complaint that are in the possession of or otherwise attainable by the complainant; or any other information the Departments may need to make a determination of facts for an investigation.

HHS may also request additional information to process a complaint under section 2799B-4 of the PHS Act regarding a health care provider, facility, or provider of air ambulance services. This information may include, but is not limited to, the bills or network status of a health care provider, health care facility, or provider of air ambulance services; information regarding the health care plan or health insurance coverage of a participant, beneficiary or enrollee; information to support a determination regarding whether the service was an emergency service or non-emergency service; documents that support the asserted facts in the complaint in the possession of, or otherwise attainable by the complainant; or any other information HHS needs to make a determination of facts for an investigation. The Departments seek comment on additional information that may be required to process a complaint.

The response may be provided directly upon receipt of the complaint, or it may be provided afterwards, though no later than 60 business days after the complaint is received. The next steps of the complaint resolution process may include referring the complainant to another appropriate state or federal resolution process, referring a complainant to the state or federal regulatory authority with enforcement jurisdiction, or initiating an investigation for enforcement action. The Departments will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of such investigations or enforcement actions, including an explanation of the findings, resolution, or any corrective action taken. The Departments will also make reasonable efforts to notify the complainant if the complaint is transferred to another state or Federal regulatory authority. The Departments seek comment on whether a complainant should receive the notification of the outcome of the complaint within a given time period and if

so within what time period a complainant should receive the notice for the purpose of this section.

The Departments intend to provide the public with a seamless experience for filing complaints by creating one system to intake all complaints on behalf of all complainants under section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and sections 2799A-1(a)(2)(B)(iv) and 2799B-4 of the PHS Act. The Departments understand that a complainant may not know which Department has enforcement jurisdiction; therefore, the Departments intend to provide one system that will direct complaints to the appropriate Department for processing, investigation, and enforcement action as necessary. The Departments will release guidance on where the public can file complaints and welcome comments on the operations, protections, user experience, or other facets of this complaint system. The Departments also seek comment on ways to ensure consumers are aware and know how to use this system.

The Departments seek to uphold Executive Order 13985 and all civil rights protections regarding non-discrimination and accessibility, as noted in prior sections. The Departments will make all reasonable efforts to implement a robust complaint process, including but not limited to, acknowledgement of receipt of a complaint, explanations of rights and information requested, explanations of findings, and referrals to other authorities. The Departments will ensure that the complaints process is accessible to all individuals, that communication and language needs are met, and that all individuals are able to understand the options available to them and information required of them. The Departments seek comment from individuals in underserved and rural communities, minority communities, and persons otherwise adversely affected by persistent poverty or inequality on specific barriers to the complaint process and solutions to address these barriers and ensure equitable access to all aspects of the complaint processes.

C. Choice of Health Care Professionals

In the Patient Protections Final Rule, the Departments finalized regulations addressing the provisions in section 2719A of the PHS Act, regarding patient protections related to choice of

health care professional and emergency services.⁶⁸ As explained earlier, the No Surprises Act amended section 2719A of the PHS Act to sunset when the new emergency services protections under the No Surprises Act take effect. The provisions of section 2719A of the PHS Act will no longer apply with respect to plan years beginning on or after January 1, 2022.⁶⁹ The No Surprises Act re-codified the patient protections related to choice of health care professional in newly added section 9822 of the Code, section 722 of ERISA, and section 2799A-7 of the PHS Act.

To reflect these statutory amendments, these interim final rules add a sunset clause to the current patient protection provisions codified in the Patient Protections Final Rule, and re-codify the provisions related to choice of health care professional without substantive change at 26 CFR 54.9822-1T, 29 CFR 2590.722, and 45 CFR 149.310. These interim final rules make minor technical edits to the original provisions for clarity.

The Departments note that, although the substantive requirements of these regulations have not changed, the No Surprises Act extends the applicability of the patient protections for choice of health care professionals to grandfathered health plans. The patient protections under section 2719A of the PHS Act apply to only non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. In contrast, the patient protections under the No Surprises Act apply generally to all group health plans and group and individual health insurance coverage, including grandfathered health plans.⁷⁰ Therefore, the requirements regarding patient protections for choice of health care professional under these interim final rules will newly apply to grandfathered health plans for plan years beginning on or after January 1, 2022. Until the requirements under section 9822 of

⁶⁸ 80 FR 72191 (November 18, 2015).

⁶⁹ Section 2719A(e) of the PHS Act states, “The provisions of this section shall not apply with respect to a group health plan, health insurance issuers, or group or individual health insurance coverage with respect to plan years beginning on or on January 1, 2022.” The Departments interpret subsection (e) to sunset section 2719A for plan years beginning on or after January 1, 2022.

⁷⁰ Section 2719A was added to the PHS Act by the Affordable Care Act. Section 1251 of the Affordable Care Act provides that certain requirements, including those in section 2719A of the PHS Act, do not apply to grandfathered health plans. The No Surprises Act does not include a comparable exception for grandfathered health plans. Furthermore, section 103(d)(2) of the No Surprises Act amends section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protections provisions, including those related choice of choice of health care professional, apply to grandfathered health plans.

the Code, section 722 of ERISA, and section 2799A-7 of the PHS Act and these interim final rules become applicable, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must continue to comply with the applicable requirements under section 2719A of the PHS Act and its implementing regulations.

D. Applicability

These interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022. The term “group health plan” includes both insured and self-insured group health plans. Group health plans include private employment-based group health plans subject to ERISA, non-federal governmental plans (such as plans sponsored by states and local governments) subject to the PHS Act, and church plans subject to the Code. Individual health insurance coverage includes coverage offered in the individual market, through or outside of an Exchange, and includes student health insurance coverage as defined at 45 CFR 147.145. In addition, as discussed further in section V of the preamble, under the OPM interim final rules, FEHB carriers must comply with the Departments’ interim final rules, subject to OPM regulation and contract provisions.

The No Surprises Act amended section 1251(a) of the Affordable Care Act to specify that sections 2799A-1, 2799A-2, and 2799A-7 of the PHS Act apply to grandfathered health plans for plan years beginning on or after January 1, 2022. Therefore, these interim final rules apply to grandfathered health plans (as defined in 26 CFR 54.9815-1251, 29 CFR 2590.715-1251, and 45 CFR 147.140). In addition, these interim final rules apply to certain non-grandfathered health insurance coverage in the individual and small group markets with respect to which CMS has announced it will not take enforcement action with respect to certain specified market

requirements even though the coverage is out of compliance with those requirements (sometimes referred to as grandfathered or transitional plans).⁷¹

These interim final rules do not apply to health reimbursement arrangements, or 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), that make reimbursements subject to a maximum fixed dollar amount for a period, as the benefit design of such plans makes concepts related to surprise billing and choice of health care professionals inapplicable.

By statute, certain plans and coverage are not subject to these interim final rules. This includes a plan or coverage consisting solely of excepted benefits,⁷² as well as short-term, limited-duration insurance. Excepted benefits are described in section 9832 of the Code, section 733 ERISA, and section 2791 of the PHS Act. Under section 2791(b)(5) of the PHS Act, short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and is, therefore, exempt from these interim final rules and the statutory provisions the regulations implement. Short-term, limited-duration insurance is defined in regulations at 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103.

These interim final rules do not apply to retiree-only plans. ERISA section 732(a) generally provides that part 7 of ERISA—and section 9831(a) of the Code generally provides that chapter 100 of the Code—does not apply to plans with less than two participants who are current employees (including retiree-only plans, which cover less than two participants who are current employees). Title XXVII of the PHS Act, as amended by the Affordable Care Act, no longer contains a parallel provision at section 2721(a) of the PHS Act. However, as explained in prior rulemaking, HHS will not enforce the requirements of title XXVII of the PHS Act with respect to non-federal governmental retiree-only plans and encourages states to adopt a similar

⁷¹ CMS Insurance Standards Bulletin Series—INFORMATION—Extension of Limited Non-Enforcement Policy through 2022 (January 19, 2021), available at <https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2022.pdf>.

⁷² Section 9831 of the Code, section 9832 of ERISA, and section 2722 of the PHS Act.

approach with respect to health insurance coverage of retiree-only plans.⁷³ HHS intends to continue to follow this same approach, including with respect to the new market reforms established in the No Surprises Act.

These interim final rules are generally applicable to traditional indemnity plans, meaning plans that do not have networks of providers or facilities. However, the Departments recognize that indemnity plans may have unique benefit designs that cause certain provisions of these interim final rules not to be relevant. For example, the requirements regarding balance billing for non-emergency services provided by nonparticipating providers at certain participating facilities would never be triggered if a plan does not have a network of participating facilities. On the other hand, such requirements could be triggered by plans that have participating facilities but do not have participating providers, either for certain provider types or at all. In addition, requirements that are unrelated to whether a plan or coverage has a network of participating providers or facilities, such as the requirement that emergency services be covered without the need for any prior authorization determination, even if the services are provided on an out-of-network basis, are applicable to traditional indemnity plans.

The Departments seek comment as to whether there are any other plans with unique benefit designs that should be exempt from all or some of these interim final rules.

IV. Overview of Interim Final Rules – Department of Health and Human Services

A. Preventing Surprise Medical Bills

1. In General

In addition to the new provisions applicable to group health plans and health insurance issuers, discussed in section III of this preamble, the No Surprises Act adds a new Part E of title XXVII of the PHS Act establishing requirements applicable to health care providers, facilities, and providers of air ambulance services. Specifically, the No Surprises Act adds new sections 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the PHS Act, which protect participants,

⁷³ 75 FR 34537, 34540 (June 17, 2010).

beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from balance bills by prohibiting nonparticipating providers, facilities, and providers of air ambulance services from billing or holding liable individuals for an amount that exceeds in-network cost sharing determined in accordance with the balance billing provisions in circumstances where the balance billing provisions apply. This includes: (1) when emergency services are provided by a nonparticipating provider or nonparticipating emergency facility; (2) when non-emergency services are provided by a nonparticipating provider at a participating health care facility; and (3) when air ambulance services are furnished by a nonparticipating provider of air ambulance services.

Under 5 U.S.C. 8902(p), as added by the No Surprises Act, sections 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the PHS Act apply to a health care provider, a facility, and a provider of air ambulance services with respect to a covered individual in a health benefits plan offered by a FEHB carrier in the same manner as they apply with respect to a participant, beneficiary, or enrollee in a group health plan or group or individual health insurance coverage offered by a health insurance issuer. These interim final rules apply to a health care provider, a facility, and a provider of air ambulance services in this same manner.⁷⁴ The applicability of these interim final rules with respect to FEHB carriers is discussed in more detail in section V of this preamble.

With respect to post-stabilization services provided by nonparticipating emergency facilities or nonparticipating providers, and non-emergency services furnished by nonparticipating providers at participating health care facilities (including off-site nonparticipating providers who furnish items or services that an individual receives as part of a visit to such health care facility), the prohibitions on balance billing do not apply if certain notice is provided to the participant, beneficiary, or enrollee, and the individual acknowledges receipt of the information in the notice and consents to waive the balance billing protections with respect to

⁷⁴ For purposes of these interim final rules, references to participants, beneficiaries, and enrollees should be construed to include covered individuals in a FEHB plan.

the nonparticipating emergency facility or nonparticipating providers to which the notice and consent apply. Under the No Surprises Act and these interim final rules, with respect to certain types of non-emergency services furnished by nonparticipating providers in a participating health care facility, the notice and consent provisions do not apply, meaning the prohibitions on balance billing apply without exception.

Given that the statute and these interim final rules authorize HHS to impose civil money penalties on facilities and providers that violate these requirements, nonparticipating providers should take steps necessary to ensure compliance by, among other actions, determining whether a given item or service is being furnished under circumstances that would trigger the surprise billing protections. For example, nonparticipating providers furnishing non-emergency services at a facility must determine whether the facility is a participating health care facility to determine whether balance billing protections apply. Relatedly, nonparticipating providers and nonparticipating emergency facilities will need to timely communicate with plans and issuers regarding when the limitations on cost sharing in these interim final rules do not apply because the notice and consent criteria (described more fully elsewhere in this preamble) have been satisfied. These HHS interim final rules address the steps providers and facilities must take to ensure the balance billing and cost-sharing protections are applied appropriately and consistently with the statute.

HHS also recognizes that compliance with these requirements may require nonparticipating providers and nonparticipating emergency facilities to refrain from billing an individual directly, even in cases that are not subject to these requirements. For example, the protections applicable to non-emergency services provided by a nonparticipating provider in a participating health care facility apply only with respect to services for which benefits are provided or covered by the plan or coverage. A nonparticipating provider may not have the information necessary to determine whether the services are a covered benefit under the plan or coverage. As a result, the nonparticipating provider may need to bill the plan or issuer directly

for the services in order to determine whether the protections apply. Otherwise, the provider risks violating the statute and these interim final rules by billing individuals. HHS understands that nonparticipating providers and facilities frequently bill individuals directly for out-of-network services, leaving the individual to submit the bill to the plan or coverage. HHS seeks comment on the impact this change will have on nonparticipating providers and facilities, and on plans and issuers receiving bills from nonparticipating providers and facilities.

In instances where a provider or facility does balance bill a participant, beneficiary, or enrollee for services in violation of the statute and these interim final rules, the Secretary of HHS (the Secretary) may impose civil money penalties in states where HHS is directly enforcing the balance billing provisions with respect to health care providers, facilities, and providers of air ambulance services. However, the statute provides that the Secretary shall waive the penalties with respect to a health care provider, facility, or provider of air ambulance services who does not knowingly violate, and should not have reasonably known it violated, the provisions, with respect to a participant, beneficiary, or enrollee, if such provider or facility, within 30 days of the violation, withdraws the bill that was in violation of such provision and reimburses the health plan or individual, as applicable, in an amount equal to the difference between the amount billed and the amount allowed to be billed under the provision, plus interest, at an interest rate determined by the Secretary. HHS intends to address enforcement of the requirements of the No Surprises Act applicable to health care providers, facilities, and providers of air ambulance services in future rulemaking.

2. Notice and Consent Exception to Prohibition on Balance Billing

Under the No Surprises Act and these interim final rules, the protections that limit cost sharing and prohibit balance billing do not apply to certain non-emergency services or to certain post-stabilization services provided in the context of emergency care, if the nonparticipating provider or nonparticipating emergency facility furnishing those items or services provides the participant, beneficiary, or enrollee, with notice, the individual acknowledges receipt of the

information in the notice, and the individual consents to waive the balance billing protections with respect to the nonparticipating emergency facility or nonparticipating providers named in the notice.

Non-emergency services furnished by a nonparticipating provider at a participating health care facility are exempt from cost sharing protections and balance billing protections when the notice and consent requirements are met. In contrast, the notice and consent exception does not apply to emergency services, other than post-stabilization services, under certain circumstances, or air ambulance services. A nonparticipating provider or nonparticipating emergency facility may obtain notice and consent from the individual in order to balance bill for post-stabilization services only in the case where a participant, beneficiary, or enrollee has received emergency services and that individual's condition has stabilized, and then only if certain additional conditions are met. Such conditions are described later in this preamble and codified at 45 CFR 149.410(b).

If an individual receives a notice, but does not provide (or revokes) consent to waive their balance billing protections, those protections remain in place. A provider or facility may, subject to other state or federal laws, refuse to treat the individual if the individual does not consent.⁷⁵ However, the cost-sharing and balance billing protections applicable to plans, issuers, providers and facilities would apply with respect to any items or services furnished by the provider or facility subsequent to the provision of the notice, and absent consent.

The requirements related to the notice and consent exception are set forth in section 2799B-2 of the PHS Act, as added by the No Surprises Act, and implemented at 45 CFR 149.410 and 45 CFR 149.420 of the HHS interim final rules, describing the requirements for post-stabilization services and non-emergency services, respectively. These interim final rules outline the requirements related to the content, method, and timing of the notice and consent

⁷⁵ HHS is aware that some providers and facilities charge fees for cancelled appointments. HHS is of the view that an individual cannot provide consent freely if a provider or facility will require the individual to pay a fee if the appointment is cancelled because the individual refuses or revokes consent.

communications; requirements related to language access; exceptions to the applicability of the notice and consent process; requirements for the retention of notice and consent documents; and requirements to notify the plan or issuer regarding consent provided by the participant, beneficiary, or enrollee.

i. Standards for Notice

The No Surprises Act and these interim final rules allow an individual to waive balance billing protections only after receiving a written notice that includes detailed information designed to ensure that individuals knowingly accept out-of-pocket charges (including charges associated with balance bills) for care received from a nonparticipating provider or nonparticipating emergency facility. In HHS's view, the option to consent to waive balance billing protections may be valuable to individuals in certain instances where they knowingly and purposefully seek care from a nonparticipating provider. For example, an individual with a complex health condition may want to be treated by a specialist who is not in their plan's network. If that specialist will not treat the individual unless the specialist can bill the individual directly for the care (and balance bill the individual), that individual may want to waive the balance billing protections. HHS seeks comment on striking the appropriate balance between allowing a specialist to refuse to treat an individual unless the specialist can balance bill the individual, while ensuring that the individual is not being pressured into waiving the balance billing protections. In HHS's view, it is important that these consumer protections do not present a barrier to obtaining out-of-network care, when an individual knowingly seeks out such care. However, it is equally important that individuals are not unknowingly subject to balance billing. Therefore, the No Surprises Act and these interim final rules allow an individual to waive balance billing protections in limited circumstances only, and only if the nonparticipating providers or nonparticipating emergency facility have provided the participant, beneficiary, or enrollee with appropriate notice explaining the applicable consumer protections and the implications of providing consent.

Section 2799B-2(d)(1)(A) of the PHS Act requires providers and facilities to use a written notice specified by HHS in guidance. Therefore, these interim final rules require providers and facilities to provide the notice using the standard notice document provided by HHS in guidance. The standard notice document will contain the elements required by the statute in a manner that is intended to be easy to read and comprehend. The notice must be provided in accordance with guidance issued by HHS. HHS is of the view that requiring use of the standard notice will help to ensure that the notice includes the content that is required to be included in the notice under the No Surprises Act and these interim final rules. Providers and facilities will need to tailor the document in each case to include information specific to the individual (for example, by identifying the provider or facility, as applicable, and adding the good faith estimated amount).

HHS is concerned that individuals may be less likely to review the notice carefully if it is embedded within other information or provided with additional consent forms. Therefore, these interim final rules require that the notice be provided with the consent document, and together these documents be given physically separate from, and not attached to or incorporated into any other documents. Providers and facilities must provide the notice within the required timeframe. The notice must be written and provided on paper, or, as practicable, electronically, as selected by the individual. The notice must meet applicable language access requirements, as described in this HHS interim final rule. A participating health care facility may provide the notice on behalf of the nonparticipating provider.⁷⁶

Authorized Representatives

The notice may be provided to the individual's authorized representative instead of the individual, and consent may be provided by the authorized representative on behalf of the

⁷⁶ However, if a facility that has agreed to provide the notice on behalf of the nonparticipating provider fails to provide the notice and obtain consent, or provides notice and obtains consent in a manner that does not satisfy the regulatory requirements in these interim final rules, the notice and consent criteria would not be considered to be met. Therefore, the cost-sharing and balance billing protections would continue to apply to the items and services furnished by the nonparticipating provider.

individual. These interim final rules specify that for purposes of 45 CFR 149.410 and 149.420, an authorized representative is an individual authorized under state law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. Although treating providers may be authorized under state law to provide consent to treatment, HHS is of the view that providers should generally not be permitted to receive notice or provide consent regarding treatment by a nonparticipating provider or facility because of the strong likelihood of an inherent financial or professional conflict of interest. These same concerns extend to employees of the facility at which the items or services are furnished. HHS is also of the view that these concerns are not warranted for providers or facility employees that are family members of the individual, because of their presumed interest in the well-being of the individual, or providers that are unaffiliated with the provider or facility furnishing the care. HHS is of the view that these limitations provide important consumer protections to ensure that an individual's authorized representative is acting in the individual's best interest rather than the interests of the provider or facility. HHS seeks comment on whether and how the term "family member" should be defined. HHS is sensitive to concerns that some individuals may not have a familial relation formally recognized under applicable state law, or other documented legal partnership with individuals whom they consider family. Therefore, when interpreting this requirement, HHS will construe the term "family member" broadly to include such individuals prior to the issuance of additional guidance.

Timing of Notice

In order to ensure that a participant, beneficiary, enrollee, or authorized representative has an opportunity to properly review and consent to a notice to receive items or services furnished by a nonparticipating provider or nonparticipating emergency facility and waive balance billing protections, the provider or facility must provide such a notice in the timeframe specified in the statute and this interim final rule. As specified in section 2799B-2(d) of the PHS

Act, if an individual schedules an appointment for such items or services at least 72 hours before the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, no later than 72 hours before the date of the appointment; and if an individual schedules an appointment for such items or services within 72 hours of the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, on the day that the appointment is made. In addition, these interim final rules specify that in the situation where an individual is provided the notice on the same day that the items or services are furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements apply.

This 3-hour requirement is intended to address situations where an individual might be asked to provide consent immediately before a provider furnishes the item or service, which may prevent their consent from being truly voluntary. Stakeholders have recommended that notice and consent procedures be unavailable when an individual visits a participating facility and receives care from a nonparticipating provider from whom the individual did not seek out services (for example, if a specialist furnishes an unexpected consultation on the recommendation of the attending physician). Stakeholders expressed concern that such providers might provide the notice at the time they appear for the consultation, and the individual might feel compelled to consent to receive care. HHS is of the view that the requirement that the notice be provided no later than 3 hours prior to furnishing items or services helps to ensure individuals can voluntarily provide informed consent, while not removing the informed consent option entirely in instances where the appointment is made the same day as the date the services are scheduled. HHS seeks comment on whether such a time limit is a reasonable approach, as well as whether the 3 hours' time requirement should be shorter or longer, in order to best ensure that consent is freely given while also facilitating timely access to care. For example, HHS is interested in understanding if there are situations where this time requirement may unduly delay

access to urgently necessary care, including in the post-stabilization care context.⁷⁷ Alternatively, HHS is interested in understanding if more time may be necessary for an individual to read, understand, and consider their options, including considering whether they can resolve prior authorization or other care management limitations, before voluntarily consenting to treatment. HHS is also interested in whether these timing requirements present barriers to providers' and facilities' ability to comply with the requirement that the notice and consent documents be provided to the individual in paper or, as practicable, electronic form, as selected by the individual.

Content of Notice

As stated previously, a provider or facility must provide the written notice using the form specified by HHS in guidance, customized to include the information specified in 45 CFR 149.420(d) (and 45 CFR 149.410(b)(2), for post-stabilization services, as applicable).

The notice must state that the health care provider furnishing the items or services is a nonparticipating provider, or that the health care facility furnishing the items or services is a nonparticipating emergency facility, as applicable, with respect to the health plan or coverage. The provider or facility will need to customize the form to identify the provider or facility by name. This will help ensure individuals understand for which specific providers or facilities they would be waiving their balance billing protections.

The notice must include the good faith estimated amount that such nonparticipating provider or nonparticipating emergency facility may charge the individual for the items and services involved, including any item or service that the nonparticipating provider reasonably expects to provide in conjunction with such items and services. In the case of a nonparticipating emergency facility, the notice must include the good faith estimate for such items or services that

⁷⁷ A provider or facility is never required to provide notice and seek consent from a participant, beneficiary, or enrollee. To the extent a provider is concerned that the 3 hours' prior requirement will result in a delay in care that is detrimental to the individual, the provider or facility can furnish the items or services, subject to the balance billing protections, rather than providing notice and seeking consent to waive the protections.

would reasonably be expected to be provided by the nonparticipating emergency facility or by nonparticipating providers as part of the visit at such facility. HHS is including the requirement regarding disclosing items and services reasonably expected to be provided in order to ensure that the participant, beneficiary, or enrollee has an accurate understanding of the cost of care. As discussed in section IV.A.2.iv of this preamble, individuals cannot waive the balance billing protections for items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished for which the nonparticipating provider or nonparticipating facility satisfied the notice and consent criteria.

Nonparticipating providers who are providing this notice are required to provide a good faith estimate for only the items or services that they would be furnishing and are not required to provide a good faith estimate for items or services furnished by other providers at the facility. However, if a nonparticipating provider has not satisfied the notice and consent criteria, balance billing and cost-sharing protections will apply to the individual with respect to items and services furnished by that nonparticipating provider, even if a different nonparticipating provider has satisfied the notice and consent criteria with respect to the same visit. If they choose, multiple nonparticipating providers that are furnishing related items and services for an individual may provide a single notice to the individual, provided that: (1) each provider's name is specifically listed on the notice document; (2) each provider includes in the notice a good faith estimate for the items and services they are furnishing, and the notice specifies which provider is providing which items and services within the good faith estimate; and (3) the individual has the option to consent to waive balance billing protections with respect to each provider separately.

HHS is of the view that an individual cannot consent to waive balance billing and cost-sharing protections unless they have been informed of their potential liability with respect to both the facility and provider charges related to receiving post-stabilization services at a nonparticipating emergency facility. Therefore, nonparticipating emergency facilities must include in the written notice the good faith estimated amount that the participant, beneficiary, or

enrollee may be charged for items or services furnished by the nonparticipating emergency facility or by nonparticipating providers with respect to the visit at such facility (including any item or service that is reasonably expected to be furnished by the nonparticipating emergency facility or nonparticipating providers in conjunction with such items or services). HHS seeks comment regarding potential challenges nonparticipating emergency facilities may have in coordinating the development of a good faith estimate on behalf of both the facility and providers. To the extent that the nonparticipating facility omits from the good faith estimate information about items and services provided by a nonparticipating provider, the notice and consent criteria will be not be considered met for items and services furnished by that provider, and the requirements in 45 CFR 149.410(a) (and the corresponding requirements on plans and issuers) would apply.

HHS is aware that nonparticipating providers and nonparticipating emergency facilities generally are unable to calculate what an individual's final out-of-pocket costs (inclusive of balance bills) will be for items and services partially or wholly covered by the individual's plan or coverage. Therefore, the good faith estimated amount should reflect the amount the provider or facility expects to charge for furnishing such items or services, even if the provider or facility intends to bill the plan or coverage directly. In calculating this good faith estimated amount, the provider or facility is expected to apply the same process and considerations used to calculate the good faith estimate that is required under section 2799B-6(2) of the PHS Act. HHS seeks comment regarding the method by which this good faith estimated amount should be calculated, and anticipates addressing this requirement in future rulemaking. The notice must make clear that the provision of the good faith estimate in the notice, or the individual's consent to be treated, does not constitute a contract with respect to the charges estimated for such items and services, or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility. HHS seeks comment regarding whether the provider or the facility should be

required to include information about what may be covered by the individual's plan or coverage and an estimate of the individual's out-of-pocket costs.

The notice must provide information about whether prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility or from the provider. HHS recognizes that there may be challenges for nonparticipating providers or facilities to identify what prior authorization and other care management limitations may apply with respect to a plan or coverage in which they do not participate. Therefore, providers and facilities may provide general information in order to satisfy this requirement, but to the extent possible, HHS encourages them to contact the issuer or plan about any such limitations so that they can include specific information in the notice. HHS interprets this statutory provision to require information on prior authorization or care management requirements to extend to care furnished by both providers and facilities, in order for participants, beneficiaries, and enrollees to understand all requirements associated with their care before they consent to treatment and balance billing. Requiring that the notice include specificity regarding prior authorization or care management requirements could improve the usefulness of the information to individuals compared to general information about what requirements may apply, but may make providing notices overly burdensome for providers and facilities. HHS seeks comment on whether providers and facilities should instead be required to include in the notice specific information about any prior authorization and care management requirements that apply to any items and services covered under the notice. HHS also seeks comment on barriers or other burdens facing nonparticipating providers or facilities in obtaining this information from a plan or issuer.

The notice must clearly state that the individual is not required to consent to receive such items or services from such nonparticipating provider or nonparticipating emergency facility. The notice must state that the individual may instead seek care from an available participating

provider or at a participating emergency facility, with respect to the plan or coverage, as applicable, and that in such cases, in-network cost-sharing amounts will apply.

In cases where post-stabilization services are being furnished by a nonparticipating provider at a participating emergency facility, the notice must include a list of any participating providers at the participating emergency facility who are able to furnish the items or services involved. The notice must inform the individual that they may be referred, at their option, to such a participating provider. HHS seeks comment regarding the format and content of the referral list to be included in the notice, including any challenges that providers may have in providing this information, and any further requirements that should be applied to providers when furnishing this information to the individual.

ii. Standards for Consent

In order to meet the notice and consent requirements of the No Surprises Act and these interim final rules, the nonparticipating provider, participating health care facility on behalf of the nonparticipating provider, or nonparticipating emergency facility must obtain from the participant, beneficiary, or enrollee the individual's acknowledgment that they consent to be treated and balance billed by the nonparticipating emergency facility or nonparticipating provider under circumstances where the individual elects to receive such items or services. The consent must be provided voluntarily, meaning that the individual has consented freely, without undue influence, fraud, or duress. An incomplete consent document will be treated as a lack of consent and balance billing protections will still apply.

As with the notice document, providers and facilities must use the standard consent document specified by HHS in guidance, and the consent document must be provided in accordance with such guidance. The consent document, specified in guidance, contains the information (or fillable fields for the information) required to be included in the consent form under these interim final rules, and described further in this section of the preamble. Providers and facilities will need to tailor the document to include information specific to the individual. In

addition, as discussed previously, these interim final rules require that the consent be accompanied by the notice document, and that these documents be given together at the same time, physically separate from and not attached to or incorporated into any other documents. The consent document must be signed (including by electronic signature) by the individual, or the individual's authorized representative.

The nonparticipating provider, participating health care facility on behalf of the nonparticipating provider, or nonparticipating emergency facility must provide the individual with a copy of the signed notice and consent in-person, or through mail or email, as selected by the individual.

The notice and consent documents must meet applicable language access requirements, as described in these interim final rules. The signed consent document must acknowledge that the individual has been provided with the written notice as described in these interim final rules, in the form selected by the individual. The signed consent document must also acknowledge that the individual has been informed that the payment made by the individual might not accrue toward meeting any limitation that the plan or coverage places on cost sharing, including an explanation that the payment might not apply to an in-network deductible or out-of-pocket maximum under the plan or coverage.

The consent document must state that, by signing the consent document, the individual agrees to be treated by the nonparticipating provider or nonparticipating emergency facility and understands that the individual may be balance billed and subject to cost-sharing requirements that apply to services furnished by nonparticipating providers or nonparticipating emergency facilities. In the case of a nonparticipating provider seeking consent, by signing the consent document, the individual agrees to waive balance billing and cost-sharing protections for only the items or services furnished by the provider or providers specifically named in the notice. In HHS's view, an individual cannot provide informed consent to waive balance billing protections with respect to an unnamed provider, as the individual would not be on notice that the individual

may be balance billed for items or services furnished by that provider. In addition, the individual may choose to consent to waive balance billing protections with respect to items or services furnished by none, some, or all of the nonparticipating providers listed in the notice.

The signed consent document must include the date on which the individual received the written notice and the date on which the individual signed such consent to be furnished the items or services covered in the notice. In order to ensure that consent is provided prior to when the item or service is received, HHS also requires that the signed consent document include the time at which the individual signed the consent.

The signed consent provided by the individual constitutes the individual's consent to the receipt of the information contained in the notice document, and includes an acknowledgement that they may be balance billed for the receipt of the items or services. The consent does not constitute a contractual agreement with regard to any estimated charge or amount included in the notice or consent document, or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility. Consent obtained by the provider or facility under this notice and consent process in no way substitutes for or modifies requirements for informed medical consent otherwise required of the provider or facility, under state law or codes of medical ethics.

The participant, beneficiary, or enrollee may revoke consent by notifying the provider or facility in writing prior to the furnishing of the items or services. If an individual revokes consent, the balance billing protections apply to applicable items or services provided after the revocation as if consent was never provided. HHS is of the view that the option to revoke consent is a critical safeguard to ensure that balance billing protections are waived only when individuals knowingly, purposefully, and freely provide informed consent. HHS seeks comment on whether additional rulemaking or guidance is needed on how an individual can revoke consent.

iii. Language Access

A nonparticipating provider or nonparticipating emergency facility providing a participant, beneficiary, or enrollee, or such individual's authorized representative, with a notice under section 2799B-2(d) of the PHS Act must make the notice available in any of the 15 most common languages in the geographic region in which the applicable facility is located. HHS is of the view that individuals cannot provide meaningful consent if they cannot understand the information provided in the written notice and consent documents. These interim final rules, therefore, also require that the notice and consent document be made available in any of the 15 most common languages in the geographic region in which the applicable facility is located. Providers and facilities will need to translate the standard notice and consent documents specified by HHS in guidance into the applicable 15 languages.

A provider or facility meets this requirement if it provides the notice and consent documents in the 15 most common languages in its state. However, HHS recognizes that in some cases, particularly in larger states or metropolitan areas, these 15 languages may not adequately represent the languages spoken by the population served by the provider or facility.⁷⁸ Therefore, the provider or facility may alternatively choose to provide the notice and consent documents in the 15 most common languages in its geographic region, which reasonably reflects the geographic region served by the applicable facility. For example, a facility that serves the greater Los Angeles area may choose to provide the notice and consent documents in the 15 most common languages within that geographic region, instead of the 15 most common languages in the state of California.

HHS considered different standards to apply in defining such geographic regions, and is seeking comment regarding the appropriate standard. HHS's objective is to implement a standard that ensures that the language accessibility requirement is responsive to the needs of the

⁷⁸ See, e.g., "Understanding Communication and Language Needs of Medicare Beneficiaries" (2017), <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf> ("The common languages in a given region, city, or town may vary greatly from those spoken in the state or in the U.S. as a whole.").

individuals served by the provider or facility, while mitigating inconsistencies in the way that such geographic regions are determined. HHS is interested in comments regarding the use of metropolitan statistical areas (MSAs),⁷⁹ hospital service areas (HSAs),⁸⁰ hospital referral regions (HRRs),⁸¹ and public use microdata areas (PUMAs),⁸² applied based on where the applicable facility is located, as well as other standards that may be well-suited for this purpose. HHS also seeks comment on what language access standards would be appropriate in circumstances where the applicable facility serves populations in multiple states.

As noted earlier in this section, HHS is of the view that individuals cannot provide meaningful consent if they cannot understand the information provided in the written notice and consent document. These interim final rules, therefore, add a language access requirement to address circumstances in which the individual cannot understand any of the 15 languages in which the notice and consent document are available. If the individual's preferred language is not among the 15 most common languages in which the documents are made available by the nonparticipating provider or nonparticipating emergency facility, or the individual cannot understand the language in which the notice and consent documents are provided, as self-reported by the individual, the notice and consent requirements described in these interim final rules are not met unless the provider or facility furnishes the individual with a qualified interpreter.

The provider or facility should provide the notice and consent documents, or the qualified interpretive services, as applicable, in the individual's self-reported, preferred language. Individuals should be asked what language they prefer to communicate in regarding health care information, for written or verbal communication, as applicable. An individual's preference

⁷⁹ <https://www.census.gov/programs-surveys/metro-micro/about.html>.

⁸⁰ <https://www.dartmouthatlas.org/faq/>.

⁸¹ <https://www.dartmouthatlas.org/faq/>.

⁸² [https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20\(PUMAs\)%20are%20non%20overlapping%2C,and%20the%20U.S.%20Virgin%20Islands.](https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20(PUMAs)%20are%20non%20overlapping%2C,and%20the%20U.S.%20Virgin%20Islands.)

might not be the same for written and verbal communication, and an individual's preference might not correlate with the individual's native language.

In interpreting the statutory requirements regarding language access in the notice and consent process, HHS recognizes communication, language, and literacy barriers are associated with decreased quality of care, poorer health outcomes, and increased utilization.⁸³ Alternatively, the use of appropriate language services and at appropriate literacy levels in health care settings is associated with increased quality of care, improved patient safety outcomes, and lower utilization of costly medical procedures.⁸⁴ HHS is of the view that it is imperative that health care providers and facilities take these efforts to provide the required notice and consent information in a manner understandable to the participant, beneficiary, or enrollee, to help achieve the goal of the statute and ensure that individuals are aware their rights and the options available to them.

Providers and facilities are also required to comply with other state and federal laws regarding language access, to the extent applicable. HHS reminds health care providers and facilities that recipients of federal financial assistance must comply with federal civil rights laws that prohibit discrimination. These laws include section 1557 of the Affordable Care Act,⁸⁵ title

⁸³ Batencourt, J.R., et al., Improving Patient Safety Systems for Patients with Limited English Proficiency: a Guide for Hospitals, Agency for healthcare Research and Quality, Publication No. 12-0041, September 2012; Proctor, K, et al., The Limited English Proficient Population: Describing Medicare, Medicaid, and Dual Beneficiaries, Health Equity Vol. 2.1, 2018; Green, AR, and Nze, C, Language-Based Inequity in Health Care: Who is the “Poor Historian”?, American Medical Association Journal of Ethics, Vol. 19, Number 3: 263-271, March 2017; Shamsi, H, et al., Implications of Language Barriers for Healthcare: A Systematic Review, Oman Medical Journal, Vol. 53, No. 2:e122, 2020; de Moissac, D., Bowen, S., Impact of Language Barriers on Quality of Care and Patient Safety for Official Language Minority Francophones in Canada, Journal of Patient Experience, Vol. 6(1) 24-32, 2019; Napoles, A.N., et al., Inaccurate Language Interpretation and its Clinical Significance in the Medical Encounters of Spanish-speaking Latinos, Med Care. 2015 November; 53(11): 940–947; Divi, C., et al., Language Proficiency and Adverse Events in U.S. Hospitals: a Pilot Study, Int'l Journal for Quality in Health Care, vol. 19, no.2; Ali, P.A. and Watson, R., Language Barriers and their Impact of Provision of Care to Patients with Limited English Proficiency: Nurses Perspective, J. Clin. Nurs., 2018 Mar;27(5-6); Flores G. Language barriers to health care in the United States. N Engl J Med 2006; 355:229-231. Ku L, and Flores G. Pay now or pay later: providing interpreter services in health care. Health Affairs. 2005;24(2): 435-444; Hampers L.C., et al. Language barriers and resource utilization in a pediatric emergency department. Pediatrics. 1999; 103(6): 1253-1256; Dewalt D.A., et al. Literacy and health outcomes: a systematic review of the literature. J Gen Intern Med. 2004;19(12):1228-1239. doi:10.1111/j.1525-1497.2004.40153.x.

⁸⁴ *Id.*

⁸⁵ 42 U.S.C. § 18116.

VI of the Civil Rights Act of 1964,⁸⁶ section 504 of the Rehabilitation Act of 1973,⁸⁷ and the Americans with Disabilities Act of 1990.⁸⁸ Section 1557 and title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services such as written translation of written content in paper or electronic form into languages other than English. Section 1557 and section 504 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Information provided through information and communication technology also must be accessible to individuals with disabilities, unless certain exceptions apply. Consistent with Executive Order 13985 and civil rights protections cited in these regulations, HHS particularly seeks comments from minority and underserved communities including those with limited English proficiency and those with disabilities who prefer information in alternate and accessible formats, and stakeholders who serve such communities, on whether the provisions and protections related to communication, language, and literacy sufficiently address barriers that exist to ensuring all individuals can read, understand, and consider their options related to notice and consent. HHS also seeks comment on what additional or alternate policies HHS may consider to help address and remove such barriers.

HHS understands that the technical nature of these protections may inherently pose barriers to individuals or their authorized representatives as they consider their options. Numerous studies have indicated that consumer comprehension of common health insurance concepts is varied and that many are not able to accurately answer questions about their health

⁸⁶ 42 U.S.C. § 2000d *et seq.*

⁸⁷ 269 U.S.C. § 794.

⁸⁸ 42 U.S.C. § 12101 *et seq.*

plan's benefit design or health care costs.⁸⁹ Individuals may also face intersecting and overlapping barriers (commonly referred to as the Social Determinants of Health) as they interact with the health care system, in addition to numerous technical forms and documents as part of receiving care. HHS solicits comment on how to best strike the balance between consumer friendliness and usability of such documents, while ensuring that they are consistent with these interim final rules and the statutory intent. HHS specifically seeks comment from those with experience in supporting individuals with low health literacy, including providers, patient advocates, and navigators, as well as those with experience in user design, in order to ensure that documents conveying these protections and opportunities to convey notice and consent are understandable and accurate.

iv. Exceptions to the Availability of Notice and Consent

The notice and consent exception is not applicable with respect to some non-emergency items or services.⁹⁰ Instead, the prohibition on balance billing and the in-network cost-sharing requirements, as described in these interim final rules, always apply with respect to those items or services. In addition, the exception for notice and consent is not applicable with respect to emergency services, except for post-stabilization services, under certain conditions.

First, as specified in section 2799B-2(b) of the PHS Act, with respect to non-emergency services, the notice and consent exception does not apply to ancillary services, which include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner; items and services provided by assistant surgeons, hospitalists, and intensivists; diagnostic services, including radiology and laboratory services; and items and services provided by a nonparticipating

⁸⁹ <https://www.policygenius.com/blog/health-insurance-literacy-survey-2019/>;
<https://www.cmu.edu/dietrich/sds/docs/loewenstein/ConsumerMisUnderstandHealthIns.pdf>

⁹⁰ 45 CFR 149.420(b) applies in cases of non-emergency services furnished by a nonparticipating provider at a participating facility and not in cases of emergency services. Additionally, 45 CFR 149.410(c) specifies that the notice and consent exception for post-stabilization services does not apply to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time a post-stabilization service is furnished for which the nonparticipating provider or nonparticipating emergency facility already satisfied the notice and consent criteria.

provider, only if there is no participating provider who can furnish such item or service at such facility.

Additionally, as specified in section 2799B-2(c) of the PHS Act, the notice and consent exception does not apply to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished for which a nonparticipating provider satisfied the notice and consent criteria. For example, even if an individual has consented to waive balance billing and in-network cost-sharing protections with respect to items and services provided by certain nonparticipating providers related to a knee surgery, that individual has not consented, nor are providers permitted to seek consent under the statute and these interim final rules, to waive those protections with respect to unforeseen, urgent medical needs that arise during the knee surgery. Because individuals lack the requisite information to provide informed consent to waive balance billing and cost-sharing protections with respect to unforeseen, urgent medical needs, HHS has determined that the rationale for the statutory exception for notice and consent to not extend to unforeseen, urgent medical needs with respect to non-emergency services also applies to unforeseen, urgent post-stabilization services. Therefore, these interim final rules provide that any notice provided and consent obtained with regard to the furnishing of certain items or services does not extend to additional items or services furnished in response to unforeseen, urgent medical needs either in the context of a nonparticipating provider in a participating facility, or of post-stabilization services.

The statute authorizes HHS to expand the definition of ancillary services to include items and services provided by other types of providers. HHS seeks comment on other ancillary services that should be considered to be made ineligible for the notice and consent exception. In particular, HHS is interested in comments on whether there are other ancillary services for which individuals are likely to have little control over the particular provider who furnishes items or services. HHS is of the view that it is with respect to these types of providers that notice and consent procedures are least appropriate. HHS is also interested in comments regarding the types

of ancillary services for which surprise bills are most common, and whether they should be added to the definition of ancillary services that are not subject to the notice and consent exception. Finally, HHS seeks comment on what criteria HHS should use in determining whether other ancillary services should be added to the definition.

Furthermore, the statute authorizes HHS to specify a list of advanced diagnostic laboratory tests that would not be considered ancillary services under this definition. Any such advanced diagnostic laboratory tests would still be subject to the surprise billing protections described in these interim final rules, but the notice and consent exemption process would also be available for these tests. HHS seeks comment on what criteria HHS should consider in determining whether an advanced diagnostic laboratory test should be excepted from the definition of ancillary services, and on any specific advanced diagnostic laboratory tests that should be considered to be made eligible for the notice and consent exception.

v. Retention of Certain Documents

Under Section 2799B-2(e) of the PHS Act and these interim final rules, nonparticipating emergency facilities, participating health care facilities, and nonparticipating providers are required to retain written notice and consent documents for at least a 7-year period after the date on which the item or service in question was furnished. Specifically, when a nonparticipating emergency facility obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, for an item or service furnished to the individual by the facility or any nonparticipating provider at such facility, the facility must retain the written notice and consent for the 7-year period. Similarly, when a participating health care facility obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, for an item or service furnished to the individual by a nonparticipating provider at such facility, the facility must retain the written notice and consent for a 7-year period. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, where the facility does not otherwise obtain the

consent on behalf of the provider, the provider may either coordinate with the facility so that the facility retains the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period. HHS interprets the retention requirement to apply to providers as well as facilities, in order to ensure that all notice and consent documents are appropriately retained, regardless of how they are obtained.

vi. Requirements to Notify the Plan or Issuer

For each item or service furnished by a nonparticipating provider or nonparticipating emergency facility, the provider (or participating facility on behalf of the nonparticipating provider) or nonparticipating emergency facility, as applicable, must timely notify the plan or issuer as to whether balance billing and in-network cost sharing protections apply to the item or service, and provide to the plan or issuer a signed copy of any signed written notice and consent documents. With respect to non-emergency services described in 45 CFR 149.410(a), the nonparticipating provider (or the participating facility on behalf of the provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility. With respect to post-stabilization services, the nonparticipating provider or nonparticipating emergency facility must notify the plan or issuer as to whether all the conditions described in 45 CFR 149.410(b) are met with respect to each of the items and services for which the bill is submitted. With respect to non-emergency services only, in instances where the nonparticipating provider bills the participant, beneficiary, or enrollee directly (where permitted under these interim final rules), the provider (or participating health care facility on behalf of the provider) may satisfy the requirement to timely notify the plan or issuer by including the notification with the bill to the individual.

In interpreting the statutory requirements, HHS recognizes that it is critical that a group health plan or health insurance issuer have knowledge of whether the balance billing and in-network cost-sharing requirements apply, including whether an item or service is furnished during a visit at a participating health care facility and if any notice was provided and consent

given what items and services were consented to, where such items and services would otherwise be subject to the balance billing protections. This information is crucial for the plan or issuer to be able to appropriately assign cost sharing and adjudicate the claim in compliance with the No Surprises Act. These interim final rules require the provider or facility to notify the plan or issuer so that the plan or issuer is aware when the balance billing and in-network cost sharing protections apply and can process the claim appropriately.⁹¹

HHS seeks comment on whether additional rulemaking would be helpful regarding the process and timing for such notification, including the definition of ‘timely,’ and what processes for conveying the notification would be most efficient, including existing processes that could be leveraged to convey the information. HHS is particularly interested in comments regarding the requirement that providers or facilities provide to the plan or issuer a copy of the signed written notice and consent document, including comments on barriers and burdens associated with such requirement, and recommendations on how best to ensure plans and issuers have information regarding the notice and consent documents without imposing undue burden on providers and facilities.

3. *Provider and Facility Disclosure Requirements Regarding Patient Protections against Balance Billing*

Section 2799B-3 of the PHS Act, added by the No Surprises Act, requires providers and facilities to provide disclosures regarding patient protections against balance billing. Among other things, the statute requires health care providers and facilities (including an emergency department of a hospital or independent freestanding emergency department) to make publicly available, post on a public website of the provider or facility (if applicable), and provide to participants, beneficiaries, and enrollees a one-page notice about the balance billing requirements

⁹¹ The Departments note that whether a provider or facility provides such a notification to the plan or issuer and whether a plan or issuer processes a claim as if notice and consent were obtained based on a provider’s notification is not determinative of whether the balance billing protections apply. A participant, beneficiary, or enrollee who is balance billed or whose cost-sharing responsibility is calculated at out-of-network rates would still be able to contend that they did not receive sufficient notice or did not provide consent, and challenge the provider or facility’s right to balance bill them, as well as and the plan or issuer’s handling of the claim.

and prohibitions that apply to the provider or facility under sections 2799B-1 and 2799B-2 of the PHS Act. The notice must include information about any applicable state requirements, and about how to contact appropriate state and federal agencies if the individual believes the provider or facility has violated the balance billing rules. These interim final rules codify the statutory requirements and information that these disclosures must include. In addition, as stated previously, under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, plans and issuers must provide information in plain language on the prohibition against balance billing and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing. These disclosure requirements are applicable for plan years beginning on or after January 1, 2022. To reduce burden and facilitate compliance with these disclosure requirements, the Departments are concurrently issuing a model disclosure notice that health care providers, facilities, group health plans, and health insurance issuers may, but are not required to, use to satisfy the disclosure requirements regarding the balance billing protections. The Departments will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act, if all other applicable requirements are met. The Departments may address these requirements in more detail in future guidance or rulemaking. Until such guidance or rulemaking implementing the requirements under section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act becomes effective and applicable, plans and issuers should exercise good-faith compliance with those statutory provisions.

These disclosures are critical to helping raise awareness and enhance the public's understanding of state and federal balance billing protections. The purpose of these disclosures is to empower individuals to better understand the balance billing protections afforded under applicable state and federal law. In addition, these disclosures are important in ensuring

individuals are able to identify violations of these interim final rules and related state law requirements and, if necessary, file complaints against providers and facilities. These disclosures further the efforts to help achieve the goals of the No Surprises Act and ensure that individuals are aware of their rights and the options available to them. These interim final rules codify the provider and facility disclosure requirements at 45 CFR 149.430. These requirements apply to health care providers and health care facilities (including independent freestanding emergency departments). These interim final rules outline requirements regarding the content of the one-page disclosure, methods for disclosure, timing of disclosure to individuals, exceptions to the requirements, and a special rule to prevent unnecessary duplication with respect to providers. These disclosure requirements do not apply to providers of air ambulance services, as section 2799B-3 of the PHS Act requires providers and facilities to disclose information regarding the requirements and prohibitions applicable to the provider or facility under sections 2799B-1 of the PHS Act (relating to balance billing for emergency services) and 2799B-2 of the PHS Act (relating to balance billing for non-emergency services furnished by nonparticipating providers at certain participating facilities), but not under section 2799B-5 of the PHS Act (relating to balance billing for air ambulance services). Although this provision does not apply to providers of air ambulance services, as the definition of health care providers in 45 CFR 149.30 excludes providers of air ambulance services, HHS encourages providers of air ambulance services to make available clear and understandable information about the requirements and prohibitions on balance billing for air ambulance services.

i. Content of Disclosure

The statute and these interim final rules require that the disclosure must include a clear and understandable statement that explains the requirements and prohibitions applicable to the provider or facility under sections 2799B-1 and 2799B-2 of the PHS Act and their implementing regulations, relating to prohibitions on balance billing in cases of emergency services and non-

emergency services performed by a nonparticipating provider at certain participating facilities as described earlier in this preamble.

In addition, the disclosure must include clear and understandable language that explains any applicable state law requirements regarding the amounts such provider or facility may charge a participant, beneficiary, or enrollee after receiving payment, if any, from a plan or coverage (with which the provider or facility does not have a contractual relationship) and any applicable cost-sharing payment from such participant, beneficiary, or enrollee.

HHS recognizes that there may be some state laws that are more protective of consumers than sections 2799B-1 and 2799B-2 of the PHS Act and their implementing regulations. For example, a state law might prohibit an individual from providing consent to be balance billed under more circumstances than those in which balance billing are prohibited under those sections and their implementing regulations. If the more protective state law causes certain provisions of sections 2799B-1 and 2799B-2 of the PHS Act and their implementing regulations to be inapplicable to the provider or facility, the provider or facility is not required to include language containing information on those inapplicable provisions in the disclosures regarding the federal requirements and prohibitions, to the extent permitted under state law. However, the provider or facility would continue to be required to include information in the disclosures about any provisions in sections 2799B-1 and 2799B-2 of the PHS Act and their implementing regulations that remain applicable to the provider or facility.

Last, the statute and these interim final rules require that the disclosure must include clear and understandable language providing contact information for the appropriate state and federal agencies that an individual may contact if the individual believes the provider or facility has violated a requirement described in the notice. If only one federal or state agency has oversight with respect to providers or facilities in the state, the disclosure may include contact information for only that agency.

In an effort to reduce the burden on health care providers and facilities, HHS has developed a model notice that health care providers and facilities may adopt, but are not required to use. HHS would consider a provider or facility that uses the HHS-developed model notice to be compliant with these federal disclosure rules with respect to the information regarding sections 2799B-1 and 2799B-2 of the PHS Act and their implementing regulations. HHS encourages states to develop model language to assist health care providers and facilities in fulfilling the disclosure requirements related to applicable state law requirements and contact information. If a state develops model language that is consistent with section 2799B-3 of the PHS Act, HHS will consider a provider or facility that makes appropriate use of the state-developed model language to be compliant with the federal requirement to include information about state law protections.

To ensure clear and understandable language for the required information, HHS encourages health care providers and facilities to utilize plain language in the disclosure statements and to consider user testing in the development of such notices.⁹² Providers and facilities must comply with applicable state or federal language access standards in providing the disclosures.⁹³ Communication and language barriers are associated with decreased quality of care and poorer health outcomes.⁹⁴ Studies have shown the benefits associated with the use of language services in clinics and hospitals include (1) increased quality of care, (2) improved patient safety outcomes, and (3) lower utilization of costly medical procedures. The presence of a language barrier is associated with higher rates of costly resource utilizations for diagnostic testing, increased emergency department visits, decreased use of preventive services, higher rates of hospitalization, and higher rates of adverse health outcomes.⁹⁵ HHS believes it is imperative

⁹² See <https://methods.18f.gov/> for information on user testing.

⁹³ See section IV.2.iii of this preamble for discussion of select federal access standards.

⁹⁴ <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan-508.pdf>

⁹⁵ See Dewalt DA, Berkman ND, Sheridan S, Lohr KN, Pignone MP. Literacy and health outcomes: a systematic review of the literature. *J Gen Intern Med.* 2004;19(12):1228-1239. doi:10.1111/j.1525-1497.2004.40153.x; Scott TL, Gazmararian JA, Williams MV, Baker DW. Health literacy and preventive health care use among Medicare enrollees in a managed care organization. *Med Care.* 2002;40:395-404; Baker DW, Parker RM, Williams MV,

that health care providers and facilities provide the required disclosure information in a clear and understandable manner to help achieve the goal of the No Surprises Act and ensure that individuals are aware of their rights related to protections against balance billing.

In addition, HHS reminds health care providers and facilities that these notices must comply with applicable federal civil rights laws, including that providers and facilities must take reasonable steps to provide meaningful access for individuals with limited English proficiency and appropriate steps to ensure effective communication with individuals with disabilities, including accessibility of information and communication technology.

HHS seeks comment on the content of the required disclosures. Consistent with Executive Order 13985 and civil rights protections cited in these interim final rules, HHS particularly seeks comments from minority and underserved communities, including from those with limited English proficiency, those who prefer information in alternate and accessible formats, those who are otherwise adversely affected by persistent poverty and inequality, as well as from stakeholders who serve these communities, on what additional barriers may exist so as to ensure individuals can read, understand, and consider disclosure information and on what policies HHS may consider for addressing and removing these barriers.

ii. Methods of Disclosure

The statute and these interim final rules require that each health care provider and facility must make the required disclosure publicly available, and (if applicable) post it on a public website of such provider or facility. In addition, providers and facilities must provide a one-page notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or individual health insurance coverage offered by a health insurance issuer.

Clark WS. Health literacy and the risk of hospital admission. *J Gen Intern Med.* 1998;13:791–8; Neira L. The importance of addressing language barriers in the US health system. Duke Center for Personalized Health Care (July 17, 2018), available at: <https://dukepersonalizedhealth.org/2018/07/the-importance-of-addressing-language-barriers-in-the-us-health-system/>.

To satisfy the requirement to post the disclosure on a public website, the disclosure or a link to such disclosure must be searchable on the provider's or facility's public website. HHS is of the view that the required disclosure information would not be publicly available unless displayed in a manner that is easily accessible, without barriers, and that ensures that the information is accessible to the general public, including that it is findable through public search engines. For example, HHS is of the view that a public website must be accessible free of charge, without having to establish a user account, password, or other credentials, accept any terms or conditions, and without having to submit any personal identifying information such as a name or email address. HHS seeks comment on whether additional regulatory standards are needed regarding what constitutes disclosure on a provider's or facility's public website to ensure the information is accessible to the public.

These interim final rules provide that a health care provider or health care facility that does not have its own website is not required to make a disclosure on a public website. HHS anticipates that most facilities subject to the requirements in sections 2799B-1 and 2799B-2 of the PHS Act would generally have a website, but recognizes that providers who furnish services at such facilities may not have their own website.

To satisfy the required disclosure to the public, providers and facilities must display the required disclosure information on a sign posted prominently at the location of the health care provider or health care facility. HHS would consider a sign to be posted prominently, if the sign were posted in a central location, such as where individuals schedule care, check-in for appointments, or pay bills. Such locations would allow individuals to be aware of the protections available before or at the time of service or payment. HHS is of the view that ensuring the individual is aware of the surprise billing protections is integral to implementation of these requirements. HHS recognizes that some providers may not have publicly accessible locations and has concluded that requiring a sign to be posted prominently at a non-publicly accessible

location would not further the purpose of providing a disclosure. Therefore, providers without a publicly accessible location are not required to make the disclosure under 45 CFR 149.430(c)(2).

Lastly, the statute and these interim final rules require that health care providers and facilities must provide the required disclosure information in a one-page notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer. The notice must be provided in-person or through mail or email, as selected by the participant, beneficiary, or enrollee. As outlined in the statute, the required disclosure to individuals must be limited to one page. HHS interprets the statute such that the disclosure notice may be one double-sided page. These interim final rules specify that the one-page disclosure must not include print smaller than 12-point font. These specifications are important to ensure that the one-page document is both designed in a form and presented in a manner that is readable by the individual or their representative and that it contains sufficient content to meet the requirements of these interim final rules.

HHS seeks comment on these disclosure methods, including whether additional methods of providing information should be required or permitted. In particular, HHS is interested in comments regarding whether posting of the disclosure information could be in a location other than a sign posted prominently at the location of the provider or facility. In addition, HHS seeks comment on ways to ensure that the required disclosure information posted on a public website is accessible to individuals.

iii. Timing of Disclosure to Individuals

These interim final rules generally require a health care provider or health care facility to provide the notice to participants, beneficiaries, or enrollees no later than the date and time on which the provider or facility requests payment from the individual (including requests for copayment made at the time of a visit to the provider or facility). In cases where the facility or provider does not request payment from the individual, the notice must be provided no later than the date on which the provider or facility submits a claim for payment to the plan or issuer.

HHS is of the view that the notice will be most effective in helping individuals understand their rights and protections under federal and state balance billing laws and protecting individuals from being improperly billed, if individuals receive the notice in accordance with this timing requirement. The requirement will ensure the disclosures are meaningful and that individuals are aware of their rights before or at the time of payment, which is likely to help individuals to avoid paying bills that are prohibited under state or federal balance billing rules. However, these interim final rules offer providers and facilities flexibility regarding when the disclosure must be provided to individuals. Providers and facilities may provide the required disclosures to individuals earlier. For example, they could provide the notice when an individual schedules an appointment, or when other standard notice disclosures (such as the Notice of Privacy Practices for Protected Health Information⁹⁶) are shared with individuals.

In developing these interim final rules, HHS considered allowing providers or facilities to provide the disclosure annually or only at the time a patient schedules a service, but wanted to ensure the timing of the disclosure was relevant to when the individual may experience a violation of the surprise billing protections. HHS encourages providers and facilities to provide individuals with the notice at a time that will maximize the notice's effectiveness.

HHS seeks comment on this timing requirement, and whether another timing requirement would be more appropriate.

iv. Exceptions

Although section 2799B-3 of the PHS Act could be interpreted to apply broadly to all health care providers and facilities, these interim final rules include two exceptions to the general requirement to provide disclosures regarding balance billing protections. First, health care providers are not required to make the disclosures required under this section if they do not furnish items or services at a health care facility, or in connection with visits at health care

⁹⁶ For requirements regarding when health care providers are required to provide the Notice of Privacy Practices, *see* 45 CFR 164.520(c).

facilities. Second, health care providers are required to provide the required disclosure only to individuals to whom they furnish items or services, and then only if such items or services are furnished at a health care facility, or in connection with a visit at a health care facility. HHS further notes that, under section 2799B-3 of the PHS Act, disclosure is required only to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer. However, as specified in 5 U.S.C. 8902(p), section 2799B-3 of the PHS Act applies to a health care provider and facility with respect to a covered individual in a FEHB plan, as well. The disclosure requirement is not required with respect to other individuals seeking care from a provider or facility.

While the statute does not explicitly provide for these exceptions, HHS is of the view that these exceptions serve two important purposes. First, they seek to avoid unnecessary confusion among individuals who otherwise might receive the disclosure under circumstances in which the balance billing protections would never apply. For instance, providing the disclosure of balance billing protections in a primary care provider's office could lead individuals to incorrectly assume balance billing protections exist where they do not. Second, by ensuring that the disclosures are targeted narrowly to relevant individuals, the exceptions aim to implement the statutory requirement without creating additional undue burden on providers and facilities.

HHS is of the view that these exceptions are consistent with balance billing requirements elsewhere in these interim final rules, related to emergency services or non-emergency services furnished by a nonparticipating provider at a participating facility. Furthermore, HHS is of the view that these exceptions do not lessen the positive impact of the disclosure requirement, as health care providers and facilities are still required to make the disclosures where balance billing is most likely to occur, which will help to ensure individuals are aware of their rights relating to consumer protections against balance billing.

HHS seeks comment on these exceptions and whether there are other scenarios that should be considered.

v. Special Rule to Prevent Unnecessary Duplication with Respect to Providers

HHS realizes there may be some instances where an individual may receive two disclosure notices – one from a provider furnishing items or services at a health care facility, and the other from the health care facility itself. These interim final rules include a special rule to streamline the provision of the required disclosure to the public and one-page notice to individuals and avoid unnecessary duplication of the disclosures with respect to providers furnishing care at a health care facility. This special rule does not apply with respect to the requirement that each health care provider and facility post the required disclosure on a public website of such provider or facility. While section 2799B-3 of the PHS Act does not explicitly provide for a special rule to prevent unnecessary duplication with respect to providers, HHS is of the view that this special rule serves an important purpose in implementing these requirements while reducing unnecessary burden and effort for providers. Furthermore, HHS is of the view that this special rule will also help reduce potential consumer confusion by allowing individuals to receive only one disclosure notice when receiving services from a provider furnishing items or services at a health care facility, both of which are subject to the disclosure requirement.

The special rule provides that to the extent a provider furnishes an item or service covered under the plan or coverage at a health care facility (including an emergency department of a hospital or independent freestanding emergency department), the provider satisfies the disclosure requirements if the facility agrees to provide the information, in the required form and manner, pursuant to a written agreement. In such instance, the disclosure must include information about the balance billing requirements and prohibitions applicable to both the facility *and* the provider. If a provider and facility have a written agreement under which the facility agrees to provide the information required under these interim final rules, and the facility fails to provide full or timely disclosure information, then the facility, but not the provider, would violate the provider disclosure requirements regarding balance billing protections. HHS is of the view that this will remove unnecessary burden and effort for the providers. HHS clarifies that a “written

agreement” may be an existing contract between the provider and facility to furnish care at the facility, if amended to provide for this special rule. Alternatively, a provider and facility may enter into a new written agreement specifically outlining the disclosure requirements regarding balance billing protections.

Providers that enter into these arrangements with facilities are encouraged to monitor the facility’s adherence to these requirements. In addition, if a provider has knowledge that the required disclosure information is not being provided in a manner specified in these interim final rules, HHS encourages the provider to work with the facility to correct the noncompliance as soon as practicable or notify the applicable state authority or HHS, in states where HHS is enforcing this requirement.⁹⁷ HHS may provide additional guidance if HHS becomes aware of situations where participants, beneficiaries, and enrollees are not being provided the required disclosure information in accordance with these interim final rules.

HHS recognizes that providers and facilities frequently bill separately for items and services furnished by the provider and the facility, and considered whether to make the special rule inapplicable in those instances. However, HHS concluded that applying the special rule is appropriate in these situations, since the disclosures are not required to be included with the bill itself. Although these interim final rules provide some flexibility around the timing of the notice, HHS anticipates that the disclosure to the individual would generally be provided at the point of care. Thus, requiring the provider and facility to separately provide notices whenever they bill separately could result in the individual receiving multiple notices for the same visit. Duplicative paperwork could overwhelm or confuse the receiving individual, which could detract from the primary purpose of clarifying and making known the protections that may apply to the individual. In addition, HHS is of the view that requiring a provider to separately post a

⁹⁷ Pursuant to section 2799B-4 of the PHS Act, states have authority to enforce the requirements of Part E of title XXVII of the PHS Act against a provider or health care facility (including a provider of air ambulance services), and HHS must enforce if a state has failed to substantially enforce the requirements. HHS intends to issue rulemaking in the future to implement section 2799B-4 of the PHS Act.

disclosure within a facility is of limited additional benefit and may present compliance challenges for providers who lack designated space within a facility. Therefore, the special rule applies regardless of whether the provider and facility bill jointly or separately.

Furthermore, since the special rule does not apply with respect to the requirement that each health care provider and facility make the required disclosure available on the public website of the provider or facility, HHS is of the view that this special rule works to achieve the goals of preventing unnecessary duplication for providers and facilities, while encouraging safeguards to ensure that individuals receive the required disclosure information and are aware of their rights. HHS is of the view that this special rule does not lessen the positive impact of the disclosure requirement. This special rule will continue to help to ensure individuals are aware of their rights relating to patient protections against surprise billing.

HHS seeks comment on this special rule and whether there are other circumstances that may warrant a special rule to prevent unnecessary duplication. In addition, HHS seeks comment on whether providers should be required, rather than encouraged, to monitor and report whether a facility is not complying with the requirement outlined in these interim final rules.

4. Surprise Billing Complaints Regarding Health Care Providers, Facilities, and Providers of Air Ambulance Services

The No Surprises Act adds section 2799B-4(b)(3) of the PHS Act, which directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services of balance billing requirements under sections 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the PHS Act and to respond to such complaints within 60 days. Therefore, the interim final rules establish an HHS-only complaints process for health care providers, facilities and providers of air ambulance services that parallels the process that the Departments are establishing through these interim final rules for plans and issuers. A more fulsome discussion of the complaints process for providers can be found in section III.B.4

of this preamble. HHS seeks comment on the complaints process for health care providers, facilities, and providers of air ambulance services described in these interim final rules.

5. Catastrophic Plans

As discussed earlier in this preamble, where the surprise billing protections apply, and the out-of-network rate exceeds the amount upon which cost sharing is based (which for emergency services provide by a nonparticipating emergency facility and for non-emergency services provided by a nonparticipating provider at a participating health care facility is the recognized amount, and for services provided by a nonparticipating provider of air ambulance services is the lesser of the billed amount or the QPA), a group health plan or health insurance issuer offering group or individual health insurance coverage must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount, even in cases where an individual has not satisfied their deductible (in which case the cost-sharing amount is the recognized amount, or the lesser of the billed amount or the QPA, as applicable). Catastrophic plans generally cannot provide benefits for any plan year until the annual limitation on cost sharing in section 1302(c)(1) of ACA is reached, other than coverage of preventive services under section 2713 of the PHS Act and at least three primary care visits. A catastrophic plan cannot comply with the new balance billing protections, specifically the obligation to make a payment to a provider or facility prior to the enrollee meeting the annual limitation on cost sharing, while satisfying the definition of a catastrophic plan at section 1302(e) of ACA. Because the No Surprises Act does not contain language eliminating catastrophic plans or exempting catastrophic plans from the law's requirements, HHS interprets the statute as permitting catastrophic plans to make payments required by sections 2799A-1 or 2799A-2 of the PHS Act without losing their status as catastrophic plans. HHS is, therefore, amending 45 CFR 156.155 in these interim final rules to specify that a catastrophic plan must provide benefits as required under sections 2799A-1 and 2799A-2 of the PHS Act and their implementing regulations, or any applicable state law providing similar surprise billing protections to individuals. Additionally, a health plan will not

fail to be treated as a catastrophic plan because the plan provides benefits prior to the annual limitation on cost sharing in section 1302(c)(1) of the ACA, as required under sections 2799A-1 and 2799A-2 of the PHS Act or any applicable state law providing similar protections to individuals.

V. Overview of Interim Final Rules – Office of Personnel Management

A. Conforming Changes for FEHB Program

The OPM interim final rules, through new 5 CFR 890.114 in subpart A, protect FEHB Program covered 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 health care facilities in certain circumstances in the same manner as the Departments' rules protect participants, beneficiaries, or enrollees. The Departments' interim final rules generally apply with respect to FEHB carriers' compliance with the No Surprises Act, except to the extent that differences are necessitated for clarification or appropriate application in the context of the FEHB Program. In considering application of the Departments' interim rules with respect to the FEHB Program, it is important to recognize that all FEHB carriers offer fully insured health benefits plans in consideration of premium payments pursuant to contract terms, and no health benefits plan is self-insured by OPM or the Federal government. OPM seeks comment on this approach and whether there should be any additional considerations in the application of these interim final rules in the context of the FEHB Program.

B. Preemption and OPM Enforcement

FEHB contract terms preempt state law with respect to coverage or benefits (including payments with respect to benefits) pursuant to 5 U.S.C. 8902(m)(1). Such preemption renders specified state law inapplicable for the purposes of determining recognized amounts and out-of-network rates under 26 CFR part 54, 29 CFR part 2590, and 45 CFR part 149. However, pursuant to bilateral negotiation of FEHB contract terms, OPM and the carrier may agree to apply state law to determine the total amount payable, rendering the state law amount, method,

or process for determining the total amount payable an effective term of the Federally-regulated, Federally-enforced contract. Accordingly, in this instance, FEHB contract terms will govern the methodology for determining recognized amounts and out-of-network rates. In the absence of a FEHB contract term incorporating a state law amount, method, or process for determining the total amount payable (including an amount determined pursuant to an All-Payer Model Agreement under section 1115A of the Social Security Act), the lesser of the billed amount or the QPA will serve as the recognized amount under the FEHB plan. Likewise, in the absence of a FEHB contract term incorporating an applicable state IDR process, the federal IDR process will govern the determination of out-of-network rates in cases of failed open negotiations.

Example A: A community-rated FEHB plan covers a specific non-emergency service that is provided to a covered individual in State A by a nonparticipating provider in a participating health care facility. Both the provider and the facility are licensed in State A. State A has a law that prohibits balance billing for non-emergency services provided to individuals by nonparticipating providers in a participating health care facility, and provides for a method for determining the cost-sharing amount and total amount payable. The law applies to health insurance issuers and providers licensed in State A and applies to the type of service provided. OPM and the FEHB carrier, through the annual contract negotiation cycle, have elected to utilize State A's law, and the FEHB health benefits plan contains a term expressly incorporating the State A law prohibiting balance billing. In this Example, the FEHB contract terms apply the state law to determine the recognized amount and the out-of-network rate.

Example B: Same facts as Example A, except that the FEHB contract terms do not incorporate or expressly refer to the balance billing law of State A. In this Example, State A's law prohibiting balance billing would be preempted by the terms of the FEHB contract. The lesser of the billed amount or QPA would apply to determine the recognized amount. The out-of-network rate would be determined through open negotiation between the nonparticipating

provider and the FEHB carrier, or in the case of failed negotiations, an amount determined under the federal IDR process.

Enforcement of these interim final rules with respect to FEHB carriers will generally be governed by OPM authorities set forth herein and 5 U.S.C. 8901 *et seq.*, 5 CFR part 890, 48 CFR chapter 16, or the carrier's FEHB contract. Any differences in terminology or other clarification will be set forth in the applicable FEHB contract.

C. Definitions

The No Surprises Act and these interim final rules include defined terms that are specific to the law's requirements and implementation. Definitions of key terms with respect to OPM's enforcement of 5 U.S.C. 8902(p) generally align with the Departments' regulations, with certain exceptions. For compliance with these provisions, the terms "group health plan or plan," "health insurance issuer or issuer," and "participant, beneficiary, or enrollee" are respectively replaced with the terms "health benefits plan," "carrier," and "enrollee or covered individual."

D. Complaints

Complaints related to the provisions under Part D of title XXVII of the PHS Act with respect to carriers and FEHB plans will generally be resolved in accordance with the Departments' interim final rules. OPM will coordinate with the Departments to ensure that complaints appropriate for OPM resolution under the FEHB Program statute, regulations or contractual authorities are referred to OPM.

E. Jurisdiction of Courts

Under 5 U.S.C. 8912, the district courts of the United States have original jurisdiction, concurrent with the United States Court of Federal Claims, of a civil action or claim against the United States founded on FEHBA. Pursuant to new paragraph (e) in 5 CFR 890.107, in the event of litigation under these interim final rules, a suit for equitable relief founded on 5 U.S.C. chapter 89 that is based on 5 U.S.C. 8902(p) and is governed by 5 CFR part 890 must be brought against

OPM by December 31 of the 3rd year after the year in which disputed services were rendered.

OPM seeks comment on amendments to its regulation on court review.

F. Applicability

OPM seeks comment on the appropriate manner of conforming compliance with sections 9816, 9817, and 9822 of the Code; sections 716, 717, and 722 of ERISA; and sections 2799A–1, 2799A–2, and 2799A–7 of the PHS Act for application to FEHB carriers, including the appropriateness and usability of the definitions and any additional changes to the Departments’ regulatory provisions that must be conformed for appropriate implementation in the FEHB Program.

For purposes of 5 U.S.C. 8902(p), the HHS interim final rules apply to health care providers, facilities, and providers of air ambulance services with respect to covered individuals in a FEHB plan in the same manner as they apply with respect to participants, beneficiaries, and enrollees in a group health plan or group or individual health insurance coverage offered by a health insurance issuer. OPM seeks comment on the appropriate manner of conforming compliance with 5 U.S.C. 8902(p) and sections 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act.

Consistent with the Departments’ approach discussed in section III.D. of this preamble, OPM will not apply these interim final rules to health benefits plans that are retiree-only plans.

VI. Waiver of Proposed Rulemaking

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries), respectively, to promulgate any interim final rules that they determine are necessary or appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and title XXVII of the PHS Act.

In addition, under section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency finds good

cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. The Secretaries and OPM Director have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until after a full public notice and comment process has been completed.

The No Surprises Act was enacted on December 27, 2020, as title I of Division BB of the Consolidated Appropriations Act, 2021. The cost-sharing and balance billing requirements on plans, issuers, health care providers, facilities, and providers of air ambulance services in the No Surprises Act apply for plan years (in the individual market, policy years) beginning on or after January 1, 2022. Although this effective date may have allowed for the regulations, if promulgated with the full notice and comment rulemaking process, to be applicable in time for the applicability date of the provisions in the No Surprises Act, this timeframe would not provide sufficient time for the regulated entities to implement the requirements. These interim final rules require plans and issuers to make significant changes to how they pay for items and services that are subject to the cost-sharing and balance billing protections, including implementing claims processing procedures to ensure that claims for items and services subject to these protections are processed in accordance with the requirements in these interim final rules. Group health plans and health insurance issuers offering group or individual health insurance coverage will have to account for these changes in establishing their premium or contribution rates, and in making other changes to the designs of plan or policy benefits. In some cases, issuers will need time to secure approval for these changes in advance of the plan or policy year in question. The Departments and OPM anticipate the plans and issuers will have already taken into consideration the statutory provisions in the No Surprises Act as they developed plan designs for 2022, and preliminary rates. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking, may allow plans and issuers to account for the finalized regulations as they finalize rates and plan offerings.

The interim final rules place new requirements on facilities, health care providers, and providers of air ambulance services regarding when they are permitted to balance bill for items and services. Such requirements include new requirements related to how providers and facilities must bill for items and services furnished on an out-of-network basis, requirements related to providing notice and obtaining consent regarding balance billing protections in certain circumstances, and requirements to disclose information on balance billing publicly, on a public website and to participants, beneficiaries, and enrollees. Health care providers and facilities require time to implement these new requirements to ensure compliance by January 1, 2022.

These interim final rules contain critical protections for participants, beneficiaries, and enrollees against balance billing. For individuals who receive balance bills, the costs can be astronomical and devastating.⁹⁸ In addition, the recipients of such bills are not the only ones who feel their impact. As discussed elsewhere in this preamble, providers have previously been able to leverage the ability to balance bill to negotiate higher in-network rates. This leads to higher premiums, higher cost sharing for consumers, and increased health expenditures.⁹⁹ One study estimated that policies to address surprise billing on a federal level could decrease health insurance premiums by one to five percent.¹⁰⁰ Additionally, consumers may delay receiving needed medical care, including for emergency medical conditions, over concern about surprise medical bills. It is therefore in the public interest that individuals receive the protections under the No Surprises Act on the date on which those protections go into effect. Accordingly, in order to allow plans, health insurance issuers, facilities, health care providers, and providers of air ambulance services sufficient time to implement these new requirements, these rules must be

⁹⁸ See, Greaney, T.L., Surprise Billing: A Window into the U.S. Health Care System, ABA Civil Rights and Social Justice Section, Human Rights Magazine (Sept. 8, 2020); Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 20173623 (July 2017, Revised January 2018).

⁹⁹ See Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 20173623 (July 2017, Revised January 2018); 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/>.

¹⁰⁰ Trish E. et al., Policies to Address Surprise Billing Can Effect Health Insurance Premiums, Am J Manag Care. 2020;26(9):401-404. <https://doi.org/10.37765/ajmc.2020.88491>.

published and available to the public well in advance of the effective date of the requirements in the No Surprises Act. Allowing time for a full notice and comment process prior to the requirements taking effect would not provide sufficient time for these entities to comply with the requirements for plan years (in the individual market, policy years) beginning on or after January 1, 2022, which would risk subjecting the public to prohibited balance bills and excess cost sharing. Additionally, plans and issuers need certainty regarding the standards of these requirements in order to begin implementation, which these interim final rules seek to provide.

Section 2723 of the PHS Act authorizes states to enforce the requirements in Part D of title XXVII of the PHS Act with respect to issuers. Section 2799B-4 of the PHS Act authorizes states to enforce the requirements in Part E of title XXVII of the PHS Act with respect to providers and health care facilities (including a provider of air ambulance services). Under both sections, HHS is required to enforce such requirements if a state fails to substantially enforce them. In order to ensure effective oversight of these new requirements as soon as they go into effect, states require time to assess the requirements contained in these interim final regulations, and notify HHS if they have not enacted legislation to enforce such requirements or they otherwise will not be enforcing such requirements. States that opt to enforce the requirements may require time to update their regulations or statutes and develop processes for enforcing the new requirements. Delaying the rules to allow for notice and comment procedures would not provide sufficient time for states to assess the new requirements and notify HHS of their ability to enforce.

In addition, the law requires the Secretaries to issue rulemaking by July 1, 2021, regarding the QPA methodology (including defining the geographic regions for purposes of the methodology); information plans or issuers must share with nonparticipating providers or facilities, as applicable, regarding the plan or issuer's determination of the QPA; and a process to receive complaints related to the QPA. Allowing time for a full notice and comment process

prior to July 1, 2021, would not have provided sufficient time for the Departments to develop and publish these rules by the statutory deadline.

For the foregoing reasons, the Departments and OPM have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules.

VII. Economic Impact and Paperwork Burden

A. Summary

These interim final rules implement provisions of the No Surprises Act, which Congress enacted as part of the CAA, that protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at certain participating facilities, and air ambulance services, under certain circumstances.

The Departments and OPM¹⁰¹ have examined the effects of these interim final rules as required by Executive Order 13563 (76 FR 3821, January 21, 2011, Improving Regulation and Regulatory Review); Executive Order 12866 (58 FR 51735, October 4, 1993, Regulatory Planning and Review); the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354); section 1102(b) of the Social Security Act (42 U.S.C. 1102(b)); section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4); Executive Order 13132 (64 FR 43255, August 10, 1999, Federalism); and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

¹⁰¹ All references to the Departments in the Economic Impact section of the preamble include OPM. The analysis includes FEHB plans.

effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects (for example, \$100 million or more in any one year), and a “significant” regulatory action is subject to review by OMB. The Departments anticipate that this regulatory action is likely to have economic impacts of \$100 million or more in at least 1 year, and thus meets the definition of an “economically significant rule” under Executive Order 12866.

Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with these interim final rules. In accordance with the provisions of Executive Order 12866, these interim final rules were reviewed by OMB.

1. Need for Regulatory Action

A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a participant, beneficiary, or enrollee receives medical services from a provider (including a provider of air ambulance services) or facility that, generally unbeknownst to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual’s coverage. Surprise bills usually occur in situations when a patient is unable to

choose a provider (including a provider of air ambulance services) or emergency facility and ensure that they receive care from only providers or emergency facilities that are participating for their coverage. A recent survey revealed that two-thirds of adults worry about being able to afford unexpected medical bills for themselves and their families, and 41 percent of adults with health insurance received a surprise medical bill in the previous 2 years.¹⁰² Surprise bills can cause significant financial hardship and cause individuals to forgo care. A project carried out by Vox, a news and opinion website, which collected emergency department medical bills reported instances of accident victims receiving care at out-of-network hospitals and receiving bills of over \$20,000.¹⁰³ These challenges may be more keenly experienced by minority and underserved communities, which are more likely to experience poor communication, underlying mistrust of the medical system, and lower levels of patient engagement than other populations.¹⁰⁴ Communities experiencing poverty and other social risk factors are particularly impacted as surprise medical bills can negatively affect individuals' abilities to eliminate debt and create wealth, and ultimately can affect a family for generations.¹⁰⁵ Effective, culturally, and linguistically tailored communication at appropriate literacy levels, along with policies that address the social risk factors and other barriers underserved communities face to accessing,

¹⁰² Pollitz K., et al., US Statistics on Surprise Medical Billing. JAMA. 2020;323(6):498. doi:10.1001/jama.2020.0065

¹⁰³ Kliff S., Surprise medical bills, the high cost of emergency department care, and the effects on patients [published online August 12, 2019]. JAMA Intern Med. doi:10.1001/jamainternmed.2019.3448.

¹⁰⁴ Butler S., Sherriff N. How poor communication exacerbates health inequities and what to do about it. Brookings Institution: Report (February 22, 2021). <https://www.brookings.edu/research/how-poor-communication-exacerbates-health-inequities-and-what-to-do-about-it/>; Hamel, L., Lopes, L., Muñana, C., Artiga, S., Brodie, M. Race, Health, and COVID-19: The Views and Experiences of Black Americans. Kaiser Family Foundation (October 2020). <https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf>; and Shen M.J., Peterson E.B., Costas-Muñiz R. *et al.* The Effects of Race and Racial Concordance on Patient-Physician Communication: A Systematic Review of the Literature. *J. Racial and Ethnic Health Disparities* **5**, 117–140 (2018). <https://doi.org/10.1007/s40615-017-0350-4>.

¹⁰⁵ Taylor, J., Racism, inequality, and health care for African Americans. The Century Foundation: Report (December 19, 2019). <https://tcf.org/content/report/racism-inequality-health-care-african-americans/>; and Chavis, B., Op-Ed: Big insurance must help end surprise medical billing. blackpressUSA (February 24, 2020). <https://blackpressusa.com/op-ed-big-insurance-must-help-end-surprise-medical-billing/>.

trusting, and understanding health care costs and coverage can reduce disparities and promote health equity.¹⁰⁶

The No Surprises Act provides federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise medical bills arise most frequently. These interim final rules implement provisions of the No Surprises Act that 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.

2. Summary of Impacts

The provisions in these interim final rules will ensure that participants, beneficiaries, and enrollees with health coverage are protected from surprise medical bills. Individuals with health coverage will gain peace of mind, experience a reduction in out-of-pocket expenses, be able to meet their deductible and out-of-pocket maximum limits sooner, and may experience increased access to care. Plans, issuers, health care providers, facilities, and providers of air ambulance services will incur costs to comply with the requirements in these interim final rules. In accordance with OMB Circular A-4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. The Departments are unable to quantify all benefits, costs, and transfers of these interim final rules but have sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these interim final rules.

TABLE 1: Accounting Statement

Benefits:
Non-Quantified:

¹⁰⁶ Pérez-Stable E.J., El-Toukhy S., Communicating with diverse patients: How patient and clinician factors affect disparities. *Patient Educ Couns.* 2018;101(12):2186-2194. doi:10.1016/j.pec.2018.08.021; McNally, M., Confronting disparities in access to healthcare for underserved populations. *MedCity News* (February 22, 2021). <https://medcitynews.com/2021/02/confronting-disparities-in-access-to-healthcare-for-underserved-populations-in-2021/>.

<ul style="list-style-type: none"> • Elimination of surprise medical bills for individuals from out-of-network medical care and air ambulance services. • Reduction in financial anxiety, including anxiety associated with medical debt, for individuals with health coverage, due to a reduction in surprise bills. • Increased access to care for individuals with health coverage that may have otherwise forgone or neglected needed treatment due to high out-of-pocket expenses, and better health outcomes as a result. Potential improved health outcomes for individuals with grandfathered health coverage due to the ability to choose their own primary care physicians, the ability to choose a pediatrician as the primary care physician for children, and the ability to receive obstetrical and gynecological care without a referral. 				
Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized (\$/year)	\$ 2,252.23 million	2021	7 percent	2021 – 2025
	\$ 2,177.12 million	2021	3 percent	2021 – 2025
<p>Quantitative:</p> <ul style="list-style-type: none"> • Costs to issuers and third-party administrators (TPAs) to comply with the requirements related to the recognized amount and QPA, estimated to be one-time costs of approximately \$4,958 million to make the necessary information technology system changes in 2021 and ongoing operational costs of \$2,047 million in 2022 and \$724 million annually from 2023 onwards. • Costs to issuers and TPAs to revise standard operating procedures and provide training to staff, estimated to be one-time costs of approximately \$12.1 million in 2021. • Costs to health care facilities and emergency facilities to revise standard operating procedures and provide training to staff, estimated to be one-time costs of \$117.2 million in 2021. • Costs to providers of air ambulance services to revise standard operating procedures and provide training to staff, estimated to be one-time costs of \$517,086 in 2021. • Costs to issuers and TPAs to share information related to QPA, estimated to be approximately \$55.4 million annually starting in 2022. • Costs to self-insured plans opting in to state law to include disclosure in plan documents, estimated to be one-time costs of approximately \$50,708 in 2022. • Costs to grandfathered health plans to provide the notice of right to designate a primary care provider, estimated to be \$4.5 million in 2022. • Costs to nonparticipating providers and nonparticipating emergency facilities to comply with requirements related to notice and consent, recordkeeping, and notice to plans and issuers, estimated to be one-time costs of approximately \$22.6 million in 2021 and ongoing costs of \$117.2 million annually starting in 2022. • Costs to individuals to read and understand the notice from nonparticipating providers and nonparticipating emergency facilities, estimated to be approximately \$99.1 million annually, starting in 2022. • Costs to health care providers and facilities to provide disclosures on patient protections against balance billing, estimated to be one-time costs of approximately \$6.8 million in 2021 and \$2.5 million annually starting in 2022. • Costs to states to develop state-specific language for patient disclosures to be provided by health care providers and facilities, estimated to be one-time costs of approximately \$10,732 in 2021. • Costs to health care facilities to enter into agreements for the facilities to provide the disclosure on patient protection on behalf of the providers, estimated to be one-time costs of approximately \$6.4 million in 2021. • Costs to plans and issuers to provide disclosure on patient protections to participants, beneficiaries and enrollees, estimated to be approximately \$699,245 in 2021 and approximately \$23.4 million annually starting in 2022. • Costs to individuals and providers to submit complaints related to surprise bills, estimated to be approximately \$97,452 annually starting in 2022. • Costs to the federal government to build a system to receive complaints and expand existing systems, estimated to be one-time costs of approximately \$19 million in 2021; and ongoing costs to process complaints, estimated to be approximately \$1.6 million in 2021, \$9.9 million in 2022, \$10.1 million in 2023 and \$10.3 million in 2024 and subsequent years. 				
Transfers:				
Non-Quantified:				
<ul style="list-style-type: none"> • Increase in health care expenditures if health care utilization increases. 				

Non-Quantified:

- Transfer from plans and issuers to participants, beneficiaries, and enrollees because plans and issuers will now pay additional amounts for some services provided by nonparticipating providers and facilities and participants, beneficiaries, and enrollees will experience a reduction in out-of-pocket expenditures.
- Potential transfer from providers, including air ambulance providers, and facilities to the participant, beneficiary or enrollee if the out-of-network rate collected is lower than what would have been collected had the provider or facility balance billed the participant, beneficiary or enrollee.

More detailed analysis forthcoming in future rulemaking:

- Potential reduction in negotiated rates for certain health care services and air ambulance services, leading to reductions in cost sharing for individuals with health coverage.
- Potential change in premiums depending on the impact on provider payments.
- Potential transfer from individuals to the federal government in the form of reduced premium tax credits if premiums decrease as a result of these interim final rules.
- Potential transfer from the federal government to individuals in the form of increased premium tax credits if premiums increase as a result of these interim final rules.

a. Prevalence of Surprise Billing

There is extensive research on the incidence of out-of-network providers and facilities billing patients for items and services furnished at in-network and out-of-network health care facilities. Most of these studies analyze claims data to identify cases that may potentially result in a surprise medical bill. The studies reveal that surprise billing is a significant issue for consumers across the country and across all types of coverage. For example, an analysis of claims data from large group health plans revealed that while rates varied by state, 18 percent of emergency department visits, on average, resulted in individuals receiving a surprise medical bill in 2017. The out-of-network charges came either from facilities or providers, or both, though the majority of the charges were from individual providers, rather than facilities.¹⁰⁷ In addition, in 2017, 16 percent of inpatient stays at in-network facilities resulted in out-of-network charges, though the rate of out-of-network billing varied by state and also between rural and urban areas. Another study revealed that admissions at in-network hospitals for surgery and mental health/substance use disorders are more likely to include out-of-network charges, and women with large-employer coverage who have had a mastectomy at an in-network facility were also more likely (21

¹⁰⁷ Pollitz K., et al., An examination of surprise medical bills and proposals to protect consumers from them, Peterson-KFF Health System Tracker, February 10, 2020, <https://www.healthsystemtracker.org/brief/an-examination-of-surprise-medical-bills-and-proposals-to-protect-consumers-from-them-3/>.

percent) to be billed for out-of-network charges.¹⁰⁸ An analysis of commercial claims data for in-network hospital admissions in 2016 found that out-of-network claims occurred in 14.5 percent of admissions, with wide variation between states.¹⁰⁹

A study using 2007-2014 claims data for group health plans indicated that in 2014, 20 percent of hospital inpatient admissions that originated in the emergency department, 14 percent of outpatient emergency department visits, and 9 percent of elective inpatient admissions were likely to result in surprise medical bills. In approximately 40 percent of inpatient admissions and more than half of outpatient cases with surprise bills, issuers paid the claims at an in-network level, so the patients were potentially billed for the remaining amount.¹¹⁰ Another study using claims data from a large issuer for the period 2010-2016 found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and that the incidence increased from 32.3 percent in 2010 to 42.8 percent in 2016. The average potential amount of the surprise medical bill also increased from \$220 in 2010 to \$628 in 2016. During the same time period, 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill, increasing from 26.3 percent in 2010 to 42 percent in 2016 and the average potential amount of the surprise medical bill increased from \$804 to \$2,040.¹¹¹

For elective surgeries, analysis of claims data from a large issuer revealed that between 2012 and 2017, an out-of-network bill occurred in over 20 percent of cases, when the primary surgeon and facility were in-network, resulting in potential balance bills ranging from \$1,255 to

¹⁰⁸ Pollitz, K. et al., Surprise Bills Vary by Diagnosis and Type of Admission, Peterson-KFF Health System tracker, December 9, 2019, <https://www.healthsystemtracker.org/brief/surprise-bills-vary-by-diagnosis-and-type-of-admission/>.

¹⁰⁹ Kennedy K. et al., Surprise out-of-network medical bills during in-network hospital admissions varied by state and medical specialty, 2016, Health Care Cost Institute, March 28, 2019, <https://healthcostinstitute.org/out-of-network-billing/oon-physician-bills-at-in-network-hospitals>.

¹¹⁰ 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.

¹¹¹ Sun EC, Mello MM, Moshfegh J, Baker LC. Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. *JAMA Intern Med.* 2019;179(11):1543–1550. doi:10.1001/jamainternmed.2019.3451.

\$3,449. Occurrences of out-of-network bills were associated with significantly higher total charges and out-of-pocket costs for patients, compared to cases without out-of-network bills.¹¹²

Researchers have also tried to estimate the amounts of surprise bills patients receive. A study using 2015 claims data from a large issuer for services provided at in-network hospitals concluded that average potential balance bills from anesthesiologists, pathologists, radiologists, and assistant surgeons were \$1,171, \$177, \$115, and \$7,420, respectively.¹¹³ Another study analyzing 2014-2017 data related to ambulatory surgical centers from three large issuers revealed that in 10 percent of cases, patients treated at in-network facilities received care from out-of-network providers, and patients may have received surprise bills in 8 percent of cases. On average, the amount of the surprise medical bill was \$1,141, and the amount increased by 81 percent over the period, from \$819 in 2014 to \$1,483 in 2017.¹¹⁴

Surprise billing is often associated with certain physician specialties, especially those whose services are not actively “shoppable” by consumers. Researchers analyzing claims data from a large issuer for the period 2010-2016 found that for emergency department visits, out-of-network bills arose frequently within the context of medical transport encounters (resulting in out-of-network bills in 85.6 percent of incidents involving ambulances) and the following physician specialties: emergency medicine (32.6 percent), anesthesiology (22.8 percent), internal medicine (23.8 percent), cardiology (20.9 percent), family practice (20.1 percent), radiology (18.1 percent), general surgery (13.3 percent), and pediatrics (8.4 percent). For inpatient admissions at in-network hospitals, in addition to medical transport (81.6 percent of cases involving ambulances), the study found that out-of-network bills arose most commonly with the following physician specialties: emergency medicine (42.6 percent of total inpatient admissions with at least 1 claim submitted by the given specialty), internal medicine (25.3 percent),

¹¹² Chhabra K.R. et al., Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery With In-Network Primary Surgeons and Facilities, 2020;323(6):538–547. doi:10.1001/jama.2019.21463.

¹¹³ 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.

¹¹⁴ Duffy E et al., Prevalence And Characteristics Of Surprise Out-of-Network Bills from Professionals in Ambulatory Surgery Centers, Health Affairs 39, No. 5, 2020. doi:10.1377/hlthaff.2019.01138.

radiology (22.6 percent), pathology (22.2 percent), cardiology (19.6 percent), anesthesiology (19.3 percent), family practice (18.2 percent), and obstetrics and gynecology (0.8 percent).¹¹⁵

While emergency medicine physicians make up only approximately 5 percent of the total number of active physicians,¹¹⁶ these studies show that emergency medical physicians have the highest percentage of out-of-network claims. Analysis of claims data for elective surgeries from a large issuer revealed that between 2012 and 2017, out-of-network claims were commonly associated with anesthesiologists (in 37 percent of cases), surgical assistants (37 percent), pathologists (22 percent), radiologists (7 percent), and medical consultants (3 percent).¹¹⁷

Another study analyzing commercial claims data for in-network inpatient admissions in 2016 found that some specialties with large shares of out-of-network bills were anesthesiology (16.5 percent), primary care (12.6 percent), and emergency medicine (11 percent) and that the specialties that most often billed as out-of-network at in-network facilities were independent labs (22.1 percent), followed by emergency medicine (12 percent).¹¹⁸ Another study analyzing 2014-2017 data related to ambulatory surgical centers from three large issuers revealed that out-of-network bills often came from anesthesiologists (44 percent of bills), certified registered nurse anesthetists (25 percent), independent laboratories (10 percent) and pathologists (3 percent).¹¹⁹

As discussed earlier in this preamble, multiple studies have shown that a large percentage of out-of-network bills come from independent laboratories. An analysis of 2008-2016 claims data for individuals with group health insurance coverage found that there was an increase in the share of out-of-network laboratory spending, and that utilization and prices for out-of-network

¹¹⁵ Sun E. et al., Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. *JAMA Intern Med.* 2019;179(11):1543–1550.

¹¹⁶ American Association of Medical Colleges. “Active Physicians by Age and Specialty.” Physician Specialty Data Report. (December 2019). <https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-age-and-specialty-2019>. The American Association of Medical Colleges estimated that among the 935,136 active physicians in the U.S. in 2019, 45,134 were emergency physicians (4.8%).

¹¹⁷ Chhabra K.R. et al., Out-of-Network Bills for Privately Insured Patients Undergoing Elective Surgery With In-Network Primary Surgeons and Facilities, 2020;323(6):538–547. doi:10.1001/jama.2019.21463.

¹¹⁸ Kennedy K et al., Surprise out-of-network medical bills during in-network hospital admissions varied by state and medical specialty, 2016, Health Care Cost Institute, March 28, 2019, <https://healthcostinstitute.org/out-of-network-billing/oon-physician-bills-at-in-network-hospitals>.

¹¹⁹ Duffy E et al., Prevalence And Characteristics Of Surprise Out-of-Network Bills from Professionals in Ambulatory Surgery Centers, *Health Affairs* 39, No. 5, 2020. doi:10.1377/hlthaff.2019.01138.

laboratory tests increased relative to in-network tests during that time period. The number of out-of-network laboratory tests increased by 18.9 percent each year, while the number of in-network laboratory tests increased by 2.3 percent per year. The study authors speculated that large suppliers of laboratory services have sufficient market power to set high out-of-network prices and utilization by clinicians may be influenced by financial incentives.¹²⁰

Providers who choose to remain out-of-network usually do so because it does not affect their patient volume. The ability to balance bill is often used as leverage by such providers to obtain higher in-network payments when they join plans' or issuers' networks. Higher in-network payments lead to higher premiums,¹²¹ higher cost sharing for consumers, and increased health care expenditures overall. For example, hospitals often outsource the staffing of their emergency departments to outside firms. A study on out-of-network billing in emergency departments looked at the behavior of the two largest emergency department staffing firms in the United States.¹²² The study found that one firm exits networks when it enters into a contract with a hospital, and bills as an out-of-network provider. The other firm temporarily exits networks and later rejoins after negotiating higher in-network payments.

Utilizations of air ambulance services also frequently result in surprise bills. A study by the Government Accountability Office (GAO) analyzed private health insurance claims from 2012 and 2017 to describe the extent to which air ambulance transports are out-of-network.¹²³ This study analyzed claims data from approximately 24,100 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.

¹²⁰ Song, Z. et al., JAMA, Out-of-Network Laboratory Test Spending, Utilization, and Prices in the US, JAMA. 2021;325(16):1674–1676. doi:10.1001/jama.2021.0720.

¹²¹ 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.

¹²² Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

¹²³ 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 payers 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.

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 changes in price between 2012 and 2017 indicate a consistent rate of increase as 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.¹²⁴ Another study found that for one of the largest providers of air ambulance services (with a market share of approximately 24 percent) the average charge increased from \$17,262.23 in 2009 to approximately \$50,199.24 by 2016.¹²⁵

As the costs associated with air ambulance transports continue to increase, the GAO reported that providers of air ambulance services report entering into more network contracts.¹²⁶ However, additional analyses find that many providers of air ambulance services, particularly those not affiliated with a hospital, do not participate in insurer 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.¹²⁷

A study using 2014-2017 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 air ambulance transports were out-of-network and approximately 40 percent of air ambulance transports resulted in potential balance bills. The bills

¹²⁴ 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>.

¹²⁵ Consumer Union. Up in the Air: Inadequate Regulation for Emergency Air Ambulance Transportation. Health Policy Report, March 2017.

¹²⁶ 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>.

¹²⁷ 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>.

averaged approximately \$19,851 in addition to the standard out-of-network cost sharing, which averaged \$561. The study also found that with out-of-network rotary-wing claims, issuers paid the providers' full billed charges approximately 48 percent of the time, at an average of \$35,733 and that for in-network providers, billed charges were paid in full only 7 percent of the time. They 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.¹²⁸

A study using claims data from a large issuer to evaluate the potential impact of out-of-network emergency medical transport services from 2013 to 2017 identified a total of 1,498,600 ambulance encounters of which 29,972 (2 percent) were air ambulance encounters, and of these 26,375 (88 percent) were rotary-wing and 3,597 (12 percent) were fixed-wing. The study further noted that the prevalence of potential surprise medical billing was an estimated 73 percent for rotary-wing (18,463) and 70 percent (2,518) for fixed-wing transports.¹²⁹ The study determined that the potential surprise billing amount for the study period totaled approximately \$456 million for air ambulance services, with a yearly average of \$91 million and a median potential surprise medical bill of approximately \$27,513.¹³⁰

A number of studies have reviewed state investigations or consumer complaints to obtain information on the amount of balance billing, and costs, associated with air ambulance transports. One study reviewed state investigations and found that in North Dakota, of 20 complaints against one provider of air ambulance services that charged a total of \$884,244 (an average of \$44,212 per flight), 33 percent of the charges were covered by insurance. In an additional nine states, the study found that 55 complaints resulted in a combined \$3.8 million in

¹²⁸ 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).

¹²⁹ Chhabra, H.R., McGuire, K., Scott, J.W., Nuliyalu, U., and Ryan, A. *Most Patients Undergoing Ground And Air Ambulance Transportation Receive Sizable Out-Of-Network Bills*. *Health Affairs* 39, NO. 5 (2020): 777-782

¹³⁰ This study found that potential surprise bills in the study period increased from \$41 million in 2013 to \$143 million in 2017. The study further found that the median potential surprise bill from air transportation nearly doubled from \$14,356 to \$27,513, or an increase of 15 percent annually, on average, after adjustment for inflation and that the prevalence ranged from 25 percent (Minnesota) to 93 percent (Massachusetts) with the size of potential surprise bills varying widely.

charges, or an average of \$77,000 per trip; and in Montana, the study found the average out-of-network rate, of the 19 bills analyzed, was \$53,397.¹³¹ The GAO further analyzed 60 consumer complaints related to air ambulance services from Maryland and North Dakota and found that from 24 complaints in Maryland the balance billed amounts ranged from \$12,300 to \$52,000 and from 36 complaints in North Dakota the balance bills ranged from \$600 to \$66,000.¹³²

b. Impact of Surprise Medical Bills

A study of out-of-network billing in emergency departments considered how some providers use the ability to bill out-of-network to increase payments. The study found that charges from out-of-network physicians in emergency departments were 637 percent of Medicare payments, which is 2.4 times higher than in-network payment rates, on average, for identical services. The study also found that emergency department physicians were paid in-network rates of 266 percent of Medicare payments, a higher percentage of Medicare payment than most other specialists.¹³³

Another study using 2017 claims data from 3 large issuers looked at expenditures on ancillary and emergency services that are most often associated with surprise bills: emergency medicine professionals, radiologists, anesthesiologists, pathologists, emergency outpatient facilities, and emergency ground ambulance services.¹³⁴ The study concluded that a 15 percent reduction in average payments for these services would lower premiums by 1.4 percent to 1.6 percent; while a reduction in average payments to 150 percent of Medicare rates would likely lower premiums by 4.5 percent to 5.1 percent. The authors estimated that for all consumers with commercial insurance coverage, 1.6 percent and 5.1 percent reductions in premiums would result in total annual savings of \$12 billion and \$38 billion, respectively.

¹³¹ Consumer Union. Up in the Air: Inadequate Regulation for Emergency Air Ambulance Transportation. Health Policy Report, March 2017.

¹³² 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>.

¹³³ Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

¹³⁴ 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.

A study using 2015 claims data from a large issuer for services provided at in-network hospitals considered the impact of policies that would prevent anesthesiologists, pathologists, radiologists, and assistant surgeons from balance billing and would reduce their in-network payments to 164 percent of Medicare payments. The study concluded that such a reduction in payment would result in savings equal to 13.4 percent of spending on physicians and 3.4 percent of spending for people with employer-sponsored coverage, approximately \$40 billion annually.¹³⁵

Surprise bills result in higher out-of-pocket expenses and cause financial anxiety and medical debt for consumers.¹³⁶ As discussed earlier in this preamble, the impact is most keenly felt by those communities experiencing poverty and other social risk factors. Potential surprise bills can vary in size, and are often large, as concluded by the studies discussed previously. A Federal Reserve report found that about 37 percent of adults in the U.S. in 2019 would not be able to pay an unexpected expense of \$400 using cash or its equivalent.¹³⁷ In a 2016 survey, among the respondents with health coverage who reported having difficulty paying medical bills, 75 percent reported that copayments, deductibles or coinsurance were more than they could afford and 32 percent had received out-of-network bills that insurance either did not cover or only partially covered.¹³⁸ Of those who had difficulty paying out-of-network bills, 69 percent said that it was a surprise bill and they had not been aware that the provider was out-of-network for their plan. Respondents also reported that bills from emergency room visits and hospitalizations often made up the largest share of the amount they owed. In the survey, respondents reported making sacrifices such as reducing expenditures on food, clothing, and

¹³⁵ 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.

¹³⁶ 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.

¹³⁷ Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2019 - May 2020, <https://www.federalreserve.gov/publications/2020-economic-well-being-of-us-households-in-2019-dealing-with-unexpected-expenses.htm>.

¹³⁸ Hamel, Liz et al., The Burden of Medical Debt: Results from the Kaiser Family Foundation/New York Times Medical Bills Survey, The Henry J. Kaiser Family Foundation, 2016, <https://www.kff.org/wp-content/uploads/2016/01/8806-the-burden-of-medical-debt-results-from-the-kaiser-family-foundation-new-york-times-medical-bills-survey.pdf>.

basic household items, using up savings, working additional jobs or hours, borrowing, changing living arrangements, and reducing or delaying vacations or major household purchases. Survey respondents also reported being contacted by collection agencies. Survey results indicated that 37 percent of individuals with household incomes less than \$50,000 (compared to 14 percent with incomes of \$100,000 or more), and 47 percent of individuals with a disability (compared to 22 percent of individuals without one) had difficulties paying medical bills, demonstrating a disproportionate impact on these populations.

In addition, out-of-network cost sharing and surprise bills usually do not count towards an individual's deductible or maximum out-of-pocket expenditure limit. Therefore, individuals with surprise bills may have difficulty reaching those limits, even though they may have high health care expenses. This can result in reduced access to care, since high medical expenses can cause individuals to delay or forgo medical care. In a 2017 survey, 64 percent of respondents reported that they had delayed care in the last year because of high medical expenses and 44 percent stated that they would forgo care if their out-of-pocket expenses would be more than \$500.¹³⁹ Another study reported that 7 percent of adults with health insurance delayed or went without care in 2019 because of cost reasons and adults who are in worse health are twice as likely to delay or forgo care because of cost reasons.¹⁴⁰ This study also reported that while 10.5 percent of all adults reported delaying or forgoing medical care due to costs, 15.1 percent of Hispanic adults and 13 percent of Non-Hispanic Black adults and 17.7 percent of adults with income below 200 percent of the federal poverty level reported the same, showing the disparate

¹³⁹ Heath, Sara, 64% of Patients Avoid Care Due to High Patient Healthcare Costs, Patient Engagement HIT, 2018, <https://patientengagementhit.com/news/64-of-patients-avoid-care-due-to-of-high-patient-healthcare-costs>.

¹⁴⁰ Amin, K et al., How Does Cost Affect Access to Care?. Peterson-KFF Health System Tracker. January 5, 2021. <https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start>.

effect of high cost of care on these communities. Another survey concluded that 65 million adults had a health issue but did not seek treatment because of cost reasons in 2018.¹⁴¹

In addition to causing financial hardship, surprise medical bills may also cause consumers to change providers in the future. Analysis of a large national sample of claims for obstetrics patients who had two deliveries covered by insurance found that 11 percent of patients received a surprise medical bill for their first delivery and were 13 percent more likely to switch hospitals for the second delivery compared to patients who did not.¹⁴²

Individuals living in rural areas experience socioeconomic and health related disparities.¹⁴³ Rural areas have fewer primary care and mental health providers and higher rates of preventable hospitalizations. Currently, there are 1,805 rural hospitals in the United States,¹⁴⁴ with 137 rural hospitals having closed since 2010.¹⁴⁵ Individuals who live in rural or geographically remote areas often must rely on air ambulance services for transfer to facilities with equipment and expertise to treat serious medical conditions. Often these transports are costly due to lack of options for in-network providers available to provide lifesaving services.¹⁴⁶ It is estimated that a quarter of Americans, approximately 85 million people, are unable to access health care in less than an hour of travel time without an air ambulance, and air ambulances may be the only viable means of transporting patients to the health care center they need.¹⁴⁷ One air ambulance provider estimates that 90 percent of their transports originate from rural areas, a

¹⁴¹ Gallup and West Health, The U.S. Healthcare Cost Crisis. 2019. <https://news.gallup.com/poll/248081/westhealth-gallup-us-healthcare-cost-crisis.aspx>.

¹⁴² Chartock, B et al., Consumers' Responses to Surprise Medical Bills in Elective Situations, *Health Affairs* 38, No.3 (2019): 425-430.

¹⁴³ North Carolina Rural Health Research Program. Rural Health Snapshot (2017). May 2017. https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/05/Snapshot2017.pdf.

¹⁴⁴ American Hospital Association, Fast Facts on U.S. Hospitals, 2021. <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁴⁵ Cecil G. Sheps Center for Health Services Research, UNC. Rural Hospital Closures. <https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/>.

¹⁴⁶ Haer, A., Senate Bill 1264: The Texan Template for the National Fight Against Balance Billing. *Texas Law Review*, 99(4), 813–838 (2021).

¹⁴⁷ Hinsdale, J.G. Report of the Council on Medical Services: Air Ambulance Regulations and Payments. American Medical Association. (2018), available at: <https://www.ama-assn.org/system/files/2018-12/i18-cms-report2.pdf>.

defined by CMS.¹⁴⁸ The GAO found that about 60 percent of rotary-wing bases added between 2012 and 2017 were located in rural areas, and about half of fixed-wing bases added between 2012 and 2017 were rural.¹⁴⁹ As a result of the growing reliance on air ambulance services, rural populations are disproportionately affected by high costs of air ambulance services.

c. Existing State Laws Regarding Balance Billing

As of February 5, 2021, 33 states have enacted legislation that provides some protection for consumers with regard to balance bills.¹⁵⁰ Laws vary by state; there are differences in the types of networks, plans, facilities, and providers that are subject to regulations, and in payment standards. While most of these states prohibit balance billing for emergency services, many of them also prohibit balance billing for certain non-emergency care furnished at in-network hospitals. It is possible that states may enact new legislation or modify existing legislation in response to the passage of the No Surprises Act and these implementing regulations.

Even within a state that has enacted such protections, those protections typically apply only to individuals enrolled in group or individual health insurance coverage, as ERISA generally preempts state laws that regulate self-insured group health plans sponsored by private employers. (Some state laws allow ERISA-covered plans to opt in to the consumer protections and process for setting payment under the state law.) In addition, states are limited in their ability to address surprise bills that involve out-of-state providers.

The air ambulance industry currently functions and operates within the health care system unlike any other entity or service, only somewhat due to the unique nature of the service. There are limited avenues for states and the U.S. Department of Transportation (DOT) to regulate their operations. States and the DOT have limited authority under the ADA to regulate the prices,

¹⁴⁸ Air Evac Lifeteam. <https://lifeteam.net/history-and-mission/#:~:text=Approximately%2090%20percent%20of%20Air,are%20based%20in%20rural%20areas.>

¹⁴⁹ 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>.

¹⁵⁰ The Commonwealth Fund, State Balance-billing Protections. https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.

routes, or services of an air carrier, including an air ambulance operator, in air transportation.¹⁵¹

The intent of the ADA was to allow the prices of air transportation services to be controlled by market forces.¹⁵² The ADA defines an “air carrier” as “a citizen of the United States undertaking by any means, directly or indirectly, to provide air transportation;” defining “air transportation” to include interstate air transportation.¹⁵³ The ADA effectively limits the ability of states to regulate the prices, routes, or services of air carriers that provide transportation services,¹⁵⁴ explicitly stating that 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.”¹⁵⁵ The Departments are not aware of any state laws regulating or limiting surprise billing or other price control measures with regard to air ambulance providers or the air ambulance industry.

State laws appear to have succeeded in providing some protection to consumers from balance billing. A study analyzing the impact of New York State’s law concluded that the law resulted in a 34 percent reduction in surprise billing in the state and lowered in-network emergency department physician payments by 9 percent.¹⁵⁶ In addition, between the implementation of the law in March 2015 and the end of 2018, the law saved individuals in the state over \$400 million with respect to emergency services.¹⁵⁷ These savings were partly due to a reduction in costs associated with emergency services and a greater incentive to participate in provider networks. In New Jersey, issuers experienced a reduction in costs associated with emergency and inadvertent out-of-network claims since the state law took effect.¹⁵⁸ The total

¹⁵¹ See <https://www.transportation.gov/individuals/aviation-consumer-protection/air-ambulance-service>.

¹⁵² Missouri Department of Insurance, Financial Institutions & Professional Registration. *Policy Brief: Health Coverage for Air Ambulance Transportation*. January 2019.

¹⁵³ 49 U.S.C. § 40102

¹⁵⁴ 49 U.S.C. § 41713

¹⁵⁵ 49 U.S.C. § 41713(b)

¹⁵⁶ Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

¹⁵⁷ New York State Department of Financial Services. New York’s Surprise Out-of-Network Protection Law: Report on the Independent Dispute Resolution Process. September 2019.

¹⁵⁸ State of New Jersey Department of Banking and Insurance. The Out-of-network Consumer Protection, Transparency, Cost Containment, and Accountability Act (P.L. 2018, c. 32) Data Reporting. As of January 31, 2021. https://www.state.nj.us/dobi/division_insurance/oonarbitration/data/210131report.html.

spending on involuntary out-of-network services were reduced by 56 percent for issuers in the individual market and by 38 percent for the issuers in the small group market. A report on California law concluded that patients were being protected from surprise medical bills in the state and that issuers had broader networks such that 80 percent to 100 percent of their hospitals and health care facilities had no nonparticipating providers practicing there.¹⁵⁹ A study on the impact of California's surprise billing law analyzed claims data for provider specialties most affected by the law (anesthesiology, diagnostic radiology, pathology, assistant surgeons, and neonatal-perinatal medicine) for the pre-implementation period from January 2014 to June 2017 and the post-implementation period from July 2017 to December 2018.¹⁶⁰ The study concluded that the share of services delivered out-of-network by the affected specialties at inpatient hospitals and ambulatory surgical centers decreased by 17 percent, ranging from a 15 percent reduction for pathology to a 31 percent decline for neonatal-perinatal medicine.

d. Benefits

Provisions in these interim final rules will protect participants, beneficiaries, or enrollees with health coverage from receiving surprise 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. Providers will no longer be able to balance bill an individual for emergency services. A provider will only be able to balance bill an individual for certain post-stabilization services, and for services performed by nonparticipating providers at certain participating facilities, if the provider or facility provides notice to the participant, beneficiary, or enrollee, and obtains the individual's consent to receive care on an out-of-network basis and be balance billed. Further, provisions ensuring all relevant

¹⁵⁹ Health Access California. Patients Protected, Providers Paid: Data From Three Years of California's Compromise to Stop Surprise Medical Bills. September 2019. <https://health-access.org/wp-content/uploads/2019/09/ha-factsheet-AB72report-final.pdf>.

¹⁶⁰ Adler, L et al. California Saw Reduction In Out-Of-Network Care From Affected Specialties After 2017 Surprise Billing law. USC-Brookings Schaeffer Initiative for Health Policy, September 26, 2019. <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/09/26/california-saw-reduction-in-out-of-network-care-from-affected-specialties-after-2017-surprise-billing-law/>.

civil rights protections are upheld and communication with consumers is accessible, in a language that is understandable, and at an appropriate literacy level, help to effectively confer these protections to minority and underserved communities.

These interim final rules also specify that for emergency services furnished by a nonparticipating provider or emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such services, as defined by the statute and in these interim final rules, while for nonparticipating providers of air ambulance services, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the billed amount or QPA, as defined by the statute and in these interim final rules.

In addition, these interim final rules require that these cost-sharing amounts be counted toward any in-network deductible or in-network out-of-pocket maximums applied under the plan or coverage in the same manner as if such cost-sharing payments were made with respect to services furnished by a participating provider, participating facility, or participating provider of air ambulance services.

Consider, for example, one case included in the project by Vox,¹⁶¹ where a victim of a violent attack was taken to an emergency facility. When the individual was able, he checked to make sure that the hospital was in-network for his plan. He was not aware, however, that the surgeon who performed emergency jaw surgery was nonparticipating for his plan and the individual received a surprise bill of \$7,924. Two other cases in the same study included an individual involved in a bike crash and another individual hit by a public bus. Both individuals

¹⁶¹ Kliff S. Surprise medical bills, the high cost of emergency department care, and the effects on patients [published online August 12, 2019]. *JAMA Intern Med.* doi:10.1001/jamainternmed.2019.3448.

were treated at the same emergency facility, which was out-of-network for both their plans and received surprise bills of \$20,243 and \$27,660, respectively. In another case, the parents of an infant who needed an inter-facility air ambulance transport for urgent surgery received a surprise medical bill of approximately \$64,000 from the air ambulance provider.¹⁶² Another case reported in the media¹⁶³ involved an expectant mother choosing an in-network hospital and a participating obstetrician for the birth of her baby. However, a nonparticipating pediatrician was called in due to a potential risk of post-delivery complications for the baby. The mother later received a surprise bill of \$636 from the pediatrician because her plan had denied the claim. In each of these situations, plans and issuers either denied the claim or paid the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services an amount that the plan or issuer considered reasonable for the services provided, and the nonparticipating provider or nonparticipating facility sent a balance bill to the individual. Under the No Surprises Act and these interim final rules, individuals in similar situations will only be responsible for in-network cost-sharing amounts and deductibles. Nonparticipating providers and nonparticipating facilities will not be able to balance bill such individuals, but instead will need to agree to an amount of payment with plans and issuers or enter into the independent dispute resolution process to determine an appropriate payment amount, if agreement on a payment amount cannot be reached.

Therefore, individuals with health coverage, including members of minority and underserved communities, are likely to see a significant reduction in balance billing, reducing one source of anxiety, financial stress, and medical debt. They will also experience a reduction in out-of-pocket expenditures, because they will only be liable for their in-network cost-sharing amounts when receiving care from nonparticipating providers, emergency facilities, and

¹⁶² Wingerter, Megan. \$64K Air Ambulance Tab Shows Limits of Surprise Billing Law. Claims Journal. January 4, 2021. <https://www.claimsjournal.com/news/national/2021/01/04/301271.htm>.

¹⁶³ Herman, Bob. Billing squeeze: Hospitals in middle as insurers and doctors battle over out-of-network charges. Modern Healthcare, August 29, 2015. <https://www.modernhealthcare.com/article/20150829/MAGAZINE/308299987/billing-squeeze-hospitals-in-middle-as-insurers-and-doctors-battle-over-out-of-network-charges>.

providers of air ambulance services, which will now count towards their deductible and maximum out-of-pocket limits, allowing individuals to reach those limits sooner. As discussed previously in this preamble, a significant number of individuals forgo or delay care due to the cost of care. A reduction in out-of-pocket expenses is likely to improve access to care and allow individuals to obtain needed treatment that they may otherwise have neglected or foregone due to concerns about the cost of care.

These interim final rules also establish a complaints process for receiving and resolving complaints related to these new surprise billing protections. The Departments are of the view that this will result in increased compliance with balance billing requirements and ensure that all individuals, including members of minority and underserved communities, are able to benefit from the protections provided by the No Surprises Act and these interim final rules. The Departments also seek comment from members of minority and underserved communities to help identify barriers to individuals exercising their rights under the No Surprises Act, as well as policies to address and remove such barriers.

The No Surprises Act extends the applicability of the patient protections for choice of health care professionals to grandfathered health plans. Participants, beneficiaries, and enrollees in grandfathered plans will now be able to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. If patients are able to choose physicians they trust and with whom they have a good relationship, they are likely to have better health outcomes.¹⁶⁴ Similarly, allowing physicians specializing in pediatrics to become primary care physicians for children will also improve health outcomes for children. The American Academy of Pediatrics (AAP) strongly supports the idea that the choice of primary care clinicians for children should include pediatricians.¹⁶⁵ In addition, a female participant,

¹⁶⁴ Olaisen, R., et al., “Assessing the Longitudinal Impact of Physician-Patient Relationship on Functional Health.” *The 18 Annals of Family Medicine* 5 (2020). <https://www.annfammed.org/content/18/5/422>.

¹⁶⁵ See AAP Policy Statement, “Guiding Principles for Managed Care Arrangements for the Health Care of Newborns, Infants, Children, Adolescents, and Young Adults”. <https://pediatrics.aappublications.org/content/pediatrics/132/5/e1452.full.pdf>.

beneficiary, or enrollee in a grandfathered plan who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology will not need an authorization or referral by the plan, issuer, or any person (including a primary care provider), which will allow them to obtain care without any delay.

The potential financial savings to consumers as a result of the protections in these interim final rules are significant. As of January 1, 2022, individuals across the country will no longer receive surprise medical bills for out-of-network emergency services, non-emergency services provided by nonparticipating providers at certain participating health care facilities, or air ambulance services. The Departments understand that some of these savings will result instead in cost transfers from participants, beneficiaries, and enrollees to group health plans or issuers, as discussed later in this preamble, or may ultimately be paid for by individuals in the form of increased health insurance premiums, which will be discussed in future rulemaking. However, the Departments anticipate that there are potentially additional cost savings for individuals, but are unaware of comprehensive national data that quantifies the potential financial benefits to individuals of the surprise billing protections included in these rules and invite stakeholders to share relevant data that would help the Departments quantify this potential consumer financial benefit.

e. Costs

Plans, issuers, health care providers, facilities, and providers of air ambulance services will incur significant costs to comply with the requirements of these interim final rules.

These interim final rules specify that for emergency services furnished by a nonparticipating provider or emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating emergency facility or participating provider were equal to the recognized amount for such

services, as defined by the No Surprises Act and these interim final rules. For nonparticipating providers of air ambulance services, cost sharing is generally calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the billed amount or the QPA, as defined by the statute and in these interim final rules. In addition, these interim final rules require that such cost sharing must also be counted toward any in-network deductible or in-network out-of-pocket maximums applied under the plan or coverage in the same manner as if such cost sharing payments were made with respect to services furnished by a participating provider, a participating facility, or a participating provider of air ambulance services.

Under these interim final rules, cost-sharing for emergency services furnished by a nonparticipating provider or emergency facility, and for non-emergency services furnished by nonparticipating providers in a participating health care facility, must be calculated based on the “recognized amount,” which is: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act, (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law, or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed amount for the services or the QPA, which generally is the median of the contracted rates of the plan or issuer for the item or service furnished in the applicable geographic region. For air ambulance services, subject to these interim final rules, plans and issuers generally must use the QPA to calculate cost sharing.

Plans and issuers will incur significant costs to calculate the recognized amount and applicable cost-sharing amount. The Departments assume that for self-insured group health plans, the costs will be incurred by third party administrators (TPAs). The Departments estimate a total 1,758 entities – 1,553 issuers¹⁶⁶ and 205 TPAs¹⁶⁷ – will be required to comply with these

¹⁶⁶ Based on data from MLR annual report for the 2019 MLR reporting year, available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

¹⁶⁷ Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

interim final rules with regard to calculating the QPA and to calculate an individual’s cost sharing liability. The Departments anticipate that issuers and TPAs will need to make changes to their information technology (IT) systems to include the capability to calculate the QPA for all out-of-network claims subject to the surprise billing protections, or the amount determined by state law or All-Payer Model Agreement, if applicable, and provide the required information related to the QPA to nonparticipating providers and nonparticipating emergency facilities. In addition, system changes will be necessary to accept and process out-of-network claims, calculate the appropriate cost-sharing amounts and include them in deductible and out-of-pocket maximum limits. The one-time cost to make system changes to include these new functionalities may be slightly lower for plans (or TPAs) and issuers already subject to state balance billing laws. The Departments estimate that each plan (or TPA) or issuer will incur one-time costs of approximately \$2.8 million, on average, to make the necessary system changes to automate the process. The total costs for all plans (or TPAs) and issuers will be approximately \$4,958 million. The Departments assume that these one-time costs will be incurred in 2021. In addition, each issuer or TPA will incur ongoing costs related to system maintenance, processing out-of-network claims and to acquire external data necessary to calculate the QPA when there is insufficient information to calculate median contracted rates starting in 2022. The Departments estimate each issuer or TPA will incur, on average, ongoing costs of \$1.2 million in 2022 and approximately \$411,840 annually starting in 2023. The total annual costs for all issuers and TPAs will be \$2,047 million in 2022 and \$724 million annually starting in 2023. See Tables 2 and 3 for more details. The Departments seek comment on these estimates.

TABLE 2: One-time IT Costs Related Costs for Plans and Issuers in 2021

		2021	
Occupation:	Hourly Wage Rate	Time (hours)	Estimated Labor Cost
IT Costs			
Project Manager/Team Lead	\$110.00	2,080	\$228,800

Scrum Master	\$110.00	3,640	\$400,400
Senior Business Analysis	\$134.00	1,560	\$209,040
UX Researcher/Service Designer	\$129.00	2,080	\$268,320
Technical Architect/Sr. Developer	\$207.00	2,080	\$430,560
DevOps Engineer/Security Engineer	\$143.00	1,560	\$223,080
Application Developer	\$111.00	9,360	\$1,038,960
Total IT Costs for Each Issuer or TPA		22,360	\$2,799,160
Total IT Costs for all Issuers and TPAs		39,308,880	\$4,920,923,280
Management Costs			
Chief Executives	\$190.24	80	\$15,219
Lawyers	\$143.18	40	\$5,727
Total		120	\$20,946
Total Management Costs for all plans and issuers		210,960	\$36,823,771
Total Costs for all Issuers and TPAs		39,519,840	\$4,957,747,051

Note: All wage rates except those related to management costs use the Contract Awarded Labor Category (CALC) tool.¹⁶⁸ Wage rates for management costs are derived using data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead).¹⁶⁹

TABLE 3: Ongoing Annual Operational Costs for Issuers and TPAs starting in 2022

Occupation:	Hourly Wage Rate	2022		2023 onwards	
		Time (hours)	Estimated Labor Cost	Time (hours)	Estimated Labor Cost
Project Manager/Team Lead	\$110.00	1,040	\$114,400	520	\$57,200
Scrum Master	\$110.00	1,300	\$143,000	520	\$57,200
Senior Business Analysis	\$134.00	780	\$104,520	0	\$0
UX Researcher/Service Designer	\$129.00	780	\$100,620	0	\$0
Technical Architect/Sr. Developer	\$207.00	1,040	\$215,280	520	\$107,640
DevOps Engineer/Security Engineer	\$143.00	780	\$111,540	520	\$74,360

¹⁶⁸ The CALC tool (<https://calc.gsa.gov/>) was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. General Services Administration (GSA) & Veterans Administration (VA) contracts. Wages obtained from the CALC database are fully burdened to account for fringe benefits and overhead costs.

¹⁶⁹ 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.

		2022		2023 onwards	
Application Developer	\$111.00	3,380	\$375,180	1,040	\$115,440
Total for Each Plan or Issuer		9,100	\$1,164,540	3,120	\$411,840
Total Costs for all Issuers and TPAs		15,997,800	\$2,047,261,320	5,484,960	\$724,014,720

Issuers and TPAs will also need to revise their standard operating procedures to include processes related to out-of-network claims, recognized amount and QPA, and provide training to their billing personnel and customer service representatives. The Departments assume that, for each issuer or TPA, a business operations specialist will need 40 hours (at an hourly labor cost of \$81.06) and a senior manager (at an hourly labor cost of \$114.24) will need 16 hours to revise the standard operating procedures, with a total cost of approximately \$5,070. In addition, the Departments assume that, on average, 10 staff at each issuer and TPA will receive 4 hours of training at a cost of \$1,824. For all 1,758 issuers and TPAs, the total cost of revising standard operating procedures and training will be \$12.1 million. The Departments assume that these one-time costs will be incurred in 2021 and that new staff will be trained as a part of the usual onboarding process at minimal additional cost and burden.

Health care and emergency facilities will also incur costs to revise their standard operating procedures and provide training to their staff regarding notice and consent requirements, patient disclosures, and out-of-network billing. The Departments estimate that there are 16,992 emergency and health care facilities (6,090 hospitals,¹⁷⁰ 270 independent freestanding emergency departments,¹⁷¹ 9,280 ambulatory surgical centers,¹⁷² and 1,352 critical access hospitals) that will incur this cost. The Departments assume that for hospital-affiliated

¹⁷⁰ American Hospital Association, Fast Facts on U.S. Hospitals, 2021. Available at <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁷¹ Emergency Medicine Network, 2018 National Emergency Department Inventory – USA. Available at <https://www.emnet-usa.org/research/studies/nedi/nedi2018/>.

¹⁷² Moriarty, A., Definitive Healthcare, How Many Ambulatory Surgery Centers are in the US?. Blog. April 10, 2019. Available at: [https://blog.definitivehc.com/how-many-asc-are-in-the-us#:~:text=Currently%2C%20there%20are%20more%20than,Healthcare's%20platform%20on%20surgery%20centers](https://blog.definitivehc.com/how-many-asc-are-in-the-us#:~:text=Currently%2C%20there%20are%20more%20than,Healthcare's%20platform%20on%20surgery%20centers.).

freestanding emergency departments, the disclosure will be developed by the parent hospitals. The Departments estimate that, on average, for each health care facility, a business operations specialist will need 40 hours and a senior manager will need 16 hours to revise the standard operating procedures, with a total cost of approximately \$5,070. In addition, on average, 10 staff at each hospital will receive 4 hours of training at a cost of approximately \$1,824. This estimate is an average of the costs and burden to be incurred by each health care facility and the Departments recognize that the costs and burden may vary depending on the size of each health care facility. The total one-time cost for 16,992 health care facilities is estimated to be approximately \$117.2 million, to be incurred in 2021, with the expectation that new staff will be trained as a part of the usual on-boarding process at minimal additional cost and burden.

Providers of air ambulance services will also incur costs to revise their standard operating procedures and provide training to their staff regarding out-of-network billing. The Departments assume that for each air ambulance provider, a business operations specialist will need 40 hours and a senior manager will need 16 hours to revise the standard operating procedures, with a total cost of approximately \$5,070. In addition, on average, 10 staff for each provider will receive 4 hours of training at a cost of approximately \$1,824. The total on-time cost for each provider of air ambulance services will be approximately \$6,894 in 2021. The total one-time cost for 75 providers of air ambulance services¹⁷³ is estimated to be approximately \$517,086, to be incurred in 2021, with the expectation that new staff will be trained as a part of the usual on-boarding process at minimal additional cost and burden.

The Departments estimate that grandfathered plans and issuers will incur a total cost of approximately \$4,516,225 in 2022 to provide the notice of right to designate a primary care provider to participants, beneficiaries, and enrollees. Self-insured plans opting in to state law will incur one-time costs of \$50,708 in 2022 to include a disclosure in plan documents. TPAs and

¹⁷³ Federal Aviation Administration, Fact Sheet – FAA Initiatives to Improve Air Ambulance Safety, 2014, https://www.faa.gov/news/fact_sheets/news_story.cfm?newsId=15794.

issuers will also incur costs of approximately \$55.4 million annually to share information related to QPAs with nonparticipating providers, nonparticipating emergency facilities, and nonparticipating providers of air ambulance services. Additionally, issuers and TPAs will incur costs to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits the disclosure regarding patient protections against balance billing. The Departments estimate a one-time cost, incurred in 2021, for all issuers and TPAs to be \$699,245 and ongoing annual costs, to begin in 2022, of approximately \$23.4 million. These costs are discussed in detail in the Paperwork Reduction Act section of this preamble.

Nonparticipating providers and nonparticipating emergency facilities may balance bill a participant, beneficiary, or enrollee if certain notice and consent requirements have been met. Providers and facilities will incur costs to prepare the notice, provide notice and receive consent from patients, retain records, and provide notice to plans and issuers. HHS estimates that the one-time cost to prepare the notice and consent documents will be approximately \$22.6 million in 2021. The ongoing annual cost to provide the notice and obtain consent, retain records and provide notice to plans and issuers is estimated to be approximately \$117.2 million starting in 2022. In addition, individuals receiving the notice and consent, where applicable, will incur costs of approximately \$99.1 million annually, starting in 2022, to read and understand the notice. These costs are discussed in detail in the Paperwork Reduction Act section of this preamble.

Health care providers and facilities will also incur costs to make publicly available, post on a public website of the provider or facility, and provide to participants, beneficiaries, and enrollees a one-page notice disclosure on patient protections against surprise billing and for providers and facilities to enter into agreements for the facilities to provide the disclosure on behalf of the providers, HHS estimates the one-time total cost, to be incurred in 2021, to be approximately \$13.1 million and the ongoing annual cost, to begin in 2022, to be approximately \$2.5 million. HHS encourages states to develop language to assist facilities in fulfilling this disclosure requirement as it applies to disclosing state protections against balance billing. HHS

estimates that the 33 states that currently have legislation to provide some protection to consumers for surprise billing will incur one-time costs of approximately \$10,732 in 2021 to develop the model language. These costs are discussed in detail in the Paperwork Reduction Act section of this preamble.

The No Surprises Act directs the Departments to establish a process to receive complaints regarding violations of the application of the QPA by group health plans and health insurance issuers offering group or individual health coverage. Individuals and entities that submit a complaint related to surprise billing will also incur costs to do so. As discussed in the Paperwork Reduction Act section of the preamble, the Departments estimate related costs to be approximately \$97,452 annually starting in 2022. In addition, the federal government will incur a one-time cost of approximately \$16 million in 2021 to build the IT system to receive and process complaints, an additional \$3 million to update existing systems in 2021, and ongoing annual costs of approximately \$1.6 million in 2021, \$9.9 million in 2022, \$10.1 million in 2023 and \$10.3 million in 2024 and subsequent years to process the complaints received and for system maintenance.

As discussed previously, individuals with protections against surprise billing are likely to experience a reduction in out-of-pocket expenses. This may increase their use of health care, which could lead to an increase in health care expenditures overall.

The Departments seek comment on these estimates and also on any additional costs incurred by plans, issuers, providers, and facilities.

f. Transfers

The provisions in these interim final rules will result in lower out-of-pocket spending by individuals. In situations where surprise bills currently occur, participants, beneficiaries, and enrollees will be responsible for only an approximation of the cost-sharing amounts they would have paid had the services been provided by a participating emergency facility, participating provider, or participating provider of air ambulance services. Plans and issuers will now be

required to pay for some expenses for items and services provided by nonparticipating facilities, providers, and providers of air ambulance services that they previously did not pay for. Thus, expenditures will shift from certain individuals to plans and issuers. In addition, it is possible the out-of-network rates collected by some providers, including air ambulance providers, and facilities will be lower than they would have been if the providers and facilities were able to balance bill the individuals. Such situations will result in transfers from providers and facilities to individuals. If there is a decrease in payments to some participating providers, as has happened for in-network emergency department physician payments in the state of New York,¹⁷⁴ there will be a transfer from those providers to plans, issuers, participants, beneficiaries, and enrollees.

As discussed previously in this preamble, these interim final rules are the first of several rules implementing the No Surprises Act and the transparency provisions of title II of Division BB of the CAA. Later this year, the Departments intend to issue additional regulations including regulations regarding the federal IDR process. The impact of the provisions of the No Surprises Act on premiums will depend on provisions not included in these interim final rules, and more detailed analysis will therefore be included in future rulemaking.¹⁷⁵

C. Regulatory Alternatives

In developing the interim final rules, the Departments considered various alternative approaches.

Determining the Cost-sharing Amount. The No Surprises Act generally requires that cost sharing for items and services subject to the surprise billing protections be based on the recognized amount. In instances where this requirement applies, the Departments considered whether it should apply where the billed charge is less than the recognized amount. In these

¹⁷⁴ Cooper, Z. et al., Surprise! Out-Of-Network Billing For Emergency Care in the United States, NBER Working Paper 23623, 2017, available at <https://www.nber.org/papers/w23623>.

¹⁷⁵ These interim final rules and the forthcoming regulations are interrelated, and in cases such as this, attribution of impacts is challenging. Inclusion of more detailed analysis in later rulemaking, rather than these interim final rules—about, for example, changes in premiums incentivized by the suite of surprise billing policies—should not be interpreted as indicating certainty that such impacts will not occur as a result of these interim final rules.

instances, assuming the plan or issuer would not pay more than the billed charge, calculating cost sharing based on the QPA (which is one way in which the recognized amount might be determined) would require a participant, beneficiary, or enrollee to pay a higher percentage in cost sharing than if such items or services had been furnished by a participating provider. However, sections 9816(a)(1)(C)(ii) and 9816(b)(1)(A) of the Code, sections 716(a)(1)(C)(ii) and 716(b)(1)(A) of ERISA, and sections 2799A-1(a)(1)(C)(ii) and 2799A-1(b)(1)(A) of the PHS Act expressly prohibit plans and issuers from applying a cost-sharing requirement that is greater than the requirement that would apply if services were provided by a participating provider or a participating emergency facility. Therefore, under these interim final rules, in circumstances where an All-Payer Model Agreement or specified state law does not apply to determine the recognized amount, cost sharing must be based on the lesser of the QPA or the amount billed by the provider for the item or service.

Methodology for Calculating the QPA. The No Surprises Act generally requires the QPA to be calculated based on the median of the contracted rates of the plan or issuer. The Departments considered whether plans and issuers should take into account the number of claims paid at the contracted rate under each contract in calculating the QPA. Doing so, however, would not result in a pure median of the contracted rates, which the Departments are of the view would most clearly follow the language of the No Surprises Act. In addition, the Departments are of the view that this approach would likely put upward pressure on the QPA, by giving greater weight to contracts of larger provider groups and facilities, which are more likely to have negotiated higher rates than small provider groups and facilities. This approach could lead to higher out-of-pocket costs for individuals.

The Departments also considered requiring plans and issuers to calculate separate median contracted rates for facilities based on the characteristics of facilities, such as by distinguishing teaching hospitals from non-teaching hospitals, rather than distinguishing only on the basis of whether the facility is an emergency department of a hospital or an independent freestanding

emergency department. The Departments decided against this approach, as doing so would result in a higher median contracted rate for facilities with higher operating costs and is not clearly contemplated in the definition of QPA under the No Surprises Act. The Departments are of the view that the different operating costs among facilities with different characteristics should not have such a dramatic impact on median contracted rates. However, the Departments recognize that payment amounts for facility charges may vary depending on whether an emergency facility is connected with a hospital. Therefore, the interim final rules allow separate median contracted rates to be calculated for emergency services based on whether the facility is an emergency department of a hospital or an independent freestanding emergency department.

With respect to calculating a separate QPA for each item and service for each geographic region, the Departments considered whether to define each geographic region as the applicable rating area as defined for purposes of the individual and small group market rating rules under PHS Act 2701 section and 45 CFR 147.102, while allowing states the flexibility to establish alternative geographic regions. However, some states define rating area by county, resulting in large numbers of rating areas in a state, some of which might include few, if any, facilities and providers. Therefore, adopting rating area as the standard for geographic region could lead to a large number of geographic regions for which a plan or issuer would have to calculate separate median contracted rates, a large number of geographic regions without sufficient information, as well as a large number of geographic regions in which the median contracted rate is influenced by outliers. Therefore, the interim final rules do not adopt this approach to defining geographic regions.

With respect to the statutory requirement for plans and issuers to calculate separate QPAs for each insurance market, including for self-insured group health plans, the Departments considered whether the market for self-insured group health plans should be limited to only self-insured group health plans offered by the same plan sponsor. However, this could lead to greater instances of a self-insured plan lacking sufficient information, so the interim final rules instead

define the self-insured market as all self-insured group health plans offered by the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity that is responsible for determining the QPA on behalf of the plan (including a third-party administrator contracted by the plan).

Participant, Beneficiary, and Enrollee Responsibility to Pay Recognized Amount Only. In instances where a participant, beneficiary, or enrollee has not satisfied their deductible, the Departments considered whether the plan or issuer should not be required to pay any portion of the out-of-network rate to the nonparticipating provider or facility. However, these interim final rules require that when the out-of-network rate exceeds the recognized amount (the amount upon which cost sharing is based), a plan or issuer must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount (the latter of which in this case would equal the recognized amount), even in instances where an individual has not satisfied their deductible. This approach is consistent with the purpose of the No Surprises Act to protect participants, beneficiaries, or enrollees from surprise balance bills that exceed in-network cost-sharing requirements. This approach is also consistent with section 102 of the No Surprises Act, which amends section 223 of the Code to specify that these payments will not prevent a plan from qualifying as a high-deductible health plan or make an individual ineligible to contribute to a health savings account.

Definition of Health Care Facility. The No Surprises Act defines a health care facility as each of the following with respect to non-emergency services: (1) a hospital (as defined in 1861(e) of the Social Security Act); (2) a hospital outpatient department; (3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act; or (5) any other facility, specified by the Departments, that provides items or services for which coverage is provided under the plan or coverage, respectively. The Departments considered whether to expand the definition of health care facility in this rulemaking, but concluded that the facilities at

which balance billing are currently most frequent are included in the current definition. The Departments anticipate continuing to monitor the prevalence of surprise billing at various facilities and may expand the definition in future rulemaking. In particular, as discussed earlier in this preamble, the Departments considered including urgent care centers in the definition of health care facility. However, given the variation across states in how urgent care centers are licensed, including the scope of services that the centers are permitted to provide, the Departments decided to instead seek comment regarding whether the definition of health care facility should be extended to urgent care centers, including those that are not licensed as facilities under state law.

With respect to the definition of participating health care facility and participating emergency facility, the Departments considered excluding facilities that had only single case agreements in place with a plan or issuer. However, the Departments are persuaded that doing so could harm participants, beneficiaries or enrollees. When individuals are provided with care, generally non-emergency items or services, under a single case agreement, they should not have to worry about potential surprise bills. Excluding facilities with single case agreements from the definitions of participating facilities and participating emergency facilities would be inconsistent with the Departments' intent to protect individuals from surprise medical bills.

Applicability of State Law. In determining how state laws around balance billing would intersect with the No Surprises Act, the Departments considered alternatives to the approach taken under these interim final rules, which seek to supplement, rather than supplant state balance billing laws. Specifically, the Departments considered whether to allow states to be more protective of consumers than the No Surprises Act with respect to whether individuals are permitted to waive balance billing protections upon notice and consent, and concluded that it is in the public interest to interpret the No Surprises Act as creating a floor regarding individuals' ability to waive balance billing protections. The Departments also considered whether state provisions allowing ERISA-covered plans to opt in to the state requirements should be

considered specified state laws for purposes of setting the recognized amount and out-of-network rate regarding ERISA-covered plans that have opted into the state programs. The Departments have concluded such deference to state law is consistent with the overarching structure of the No Surprises Act. The Departments also considered allowing providers, facilities and providers of air ambulance services to opt in to state laws (as allowed under state laws), but decided to instead seek comments on this approach, as discussed earlier in this preamble.

Notice and Consent Exception to Prohibition on Balance Billing. Under the No Surprises Act and these interim final rules, the protections that limit cost sharing and prohibit balance billing do not apply to certain non-emergency services or to certain post-stabilization services provided in the context of emergency care, if the nonparticipating provider or nonparticipating emergency facility furnishing those items or services provides the participant, beneficiary, or enrollee, with certain notice, the individual acknowledges receipt of the information in the notice, and the individual consents to be treated by the nonparticipating emergency facility or nonparticipating provider. These interim final rules establish the conditions under which notice and consent may be provided for certain non-emergency and post-stabilization services. The Departments considered a number of additional conditions under which the notice and consent exception would not be permitted, such as if the individual were experiencing pain, or under the influence of alcohol or drugs, including the use or administration of prescribed medications. The Departments are of the view that these factors are critical considerations for whether an individual is able to provide informed consent, and concluded that these are factors that a provider would be expected to assess when determining if the individual is capable of understanding the information provided in the notice and the implications of consenting. The HHS interim final rules therefore establish requirements related to the notice and consent exception. HHS considered a number of alternatives in developing these interim final rules. HHS considered different standards to apply in defining geographic regions for purposes of language access requirements. The HHS interim final rules require providers and facilities to provide the

notice and consent documents in the 15 most common language in the state, or in a geographic region, which reasonably reflects the geographic region served by the applicable facility. HHS also considered the use of MSAs,¹⁷⁶ hospital service areas (HSAs),¹⁷⁷ hospital referral regions (HRRs),¹⁷⁸ and public use microdata areas (PUMAs),¹⁷⁹ applied based on where the applicable facility is located. These geographic regions might better reflect a facility's service area than a state. However, HHS is of the view that allowing providers and facilities to use the state as the geographic region would reduce burden, and concluded that the standard in the HHS interim final rules provides sufficient flexibility for providers and facilities to determine how best to serve their population. HHS considered requiring that a provider or facility that uses a region other than a state must use a geographic region smaller than a state, but determined this approach would not adequately address the needs to facilities that serve populations that cross state borders. HHS also considered alternatives regarding the inapplicability of the notice and consent exception to ancillary services. HHS considered expanding the definition of ancillary services to include other services for which surprise billing frequently occurs. In particular, stakeholders raised concerns about providers who deliver services to individuals during inpatient stays, but who the individual has little involvement in selecting. These included, for example, providers furnishing mental health services, cardiology services, and rehabilitative services. The Departments are concerned about surprise bills that arise in these situations, but prefer to further consider the recommendation. Individuals may have strong preferences to select these types of providers for out-of-network care, and it is therefore not clear whether they would be appropriate to include among the types of specialties for which notice and consent to be balance billed is prohibited.

¹⁷⁶ <https://www.census.gov/programs-surveys/metro-micro/about.html>.

¹⁷⁷ <https://www.dartmouthatlas.org/faq/>.

¹⁷⁸ <https://www.dartmouthatlas.org/faq/>.

¹⁷⁹ [https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20\(PUMAs\)%20are%20non%20overlapping%2C,and%20the%20U.S.%20Virgin%20Islands.](https://www.census.gov/programs-surveys/geography/guidance/geo-areas/pumas.html#:~:text=Public%20Use%20Microdata%20Areas%20(PUMAs)%20are%20non%20overlapping%2C,and%20the%20U.S.%20Virgin%20Islands.)

Applicability date. The Departments considered delaying the applicability date of these interim final rules in response to stakeholder feedback regarding the challenges of coming into compliance with these interim final rules by January 1, 2022. The Departments recognize the challenges that providers (including providers of air ambulance services), facilities, plans, and issuers will face in making the necessary changes to comply with these new requirements. However, delaying the applicability date would have significant ramifications for participants, beneficiaries, and enrollees and would continue to leave them vulnerable to surprise bills. Therefore, the Departments concluded that it is in the public interest to require these interim final rules to be applicable in accordance with the applicability dates in the No Surprises Act.

Provider Disclosure Requirements Regarding Patient Protections against Balance Billing. Section 2799B-3 of the PHS Act, as added by the No Surprises Act, requires providers and facilities to provide disclosures regarding patient protections against balance billing. These interim final rules include provisions to limit this disclosure requirement to certain providers and facilities, and with respect to certain individuals. These interim final rules also include a special rule to limit unnecessary duplication, so that a facility's disclosure may satisfy the disclosure requirement on behalf of providers in certain circumstances. HHS considered applying the disclosure requirement more broadly. However, HHS determined that a broader application of the disclosure requirements would increase the administrative costs associated with the requirement, without commensurate benefits to individuals. Rather, HHS was concerned that requiring the disclosure be made by facilities and providers in circumstances where the protections against balance billing would not apply could create consumer confusion about their rights under the No Surprises Act. Additionally, HHS determined that requiring providers to provide a disclosure when furnishing services at a facility that was also required to provide a disclosure was unnecessary and could be overwhelming to consumers. If providers furnishing services at a facility were required to provide a disclosure as well, at the very least, the cost of printing and materials for the notices would have doubled, for an additional \$2.5 million in costs.

If, in addition, providers had to develop the notices they provided, there would have been additional costs. If all providers were required to provide a notice, regardless of whether the services are furnished at a provider's office or a health care facility, then in addition to the 39,690,940 individuals treated in the emergency facilities,¹⁸⁰ 526,685,200 individuals visiting a provider's office or a health care facility would have been provided a disclosure, for a total of 566,376,140 disclosures.¹⁸¹ The cost to print the disclosures would have been approximately \$28.3 million, approximately \$25.8 million more than it is estimated to be under the provisions in these interim final rules.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (PRA), HHS is required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that HHS solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of HHS' 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.

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

¹⁸⁰ Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits. <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide#export>

¹⁸¹ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

1. Wage Estimates

To derive wage estimates, the Departments 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.¹⁸² Table 4 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 the Departments are of the view that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 4: Wage Rates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hour)	Fringe Benefits and Overhead (\$/hour)	Adjusted Hourly Wage (\$/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43-6014	\$19.43	\$19.43	\$38.86
Lawyer	23-1011	\$71.59	\$71.59	\$143.18
All Occupations	00-0000	\$27.07	\$27.07	\$54.14
Computer Programmers	15-1251	\$45.98	\$45.98	\$91.96
Medical Secretaries and Administrative Assistants	43-6013	\$18.75	\$18.75	\$37.50
Human Resources Specialists	13-1071	\$33.38	\$33.38	\$66.76
Business Operations Specialist	13-1198	\$38.57	\$38.57	\$77.14
General and Operations Manager	11-1021	\$59.15	\$59.15	\$118.30
Compensation and Benefits Manager	11-3111	\$65.94	\$65.94	\$131.88
Computer and Information Systems Managers	11-3021	\$77.76	\$77.76	\$155.52

2. ICRs Regarding Information to be Shared About QPA (45 CFR 149.140(d))

¹⁸² 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.

These interim final rules require plans and issuers to provide certain information regarding the QPA to nonparticipating providers, or nonparticipating emergency facilities in cases in which the recognized amount with respect to an item or service furnished by the provider or facility is the QPA (and in all cases subject to these rules for nonparticipating providers of air ambulance services). Specifically, plans and issuers must provide the following information to providers (including air ambulance providers) and facilities, when making an initial payment or notice of denial of payment: (1) the QPA for each item or service involved; (2) a statement certifying that the plan or issuer has determined that the QPA applies for the purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and each QPA was determined in compliance with the methodology established in these interim final rules; (3) a statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and (4) contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service. Additionally, upon request of the provider or facility, the plan or issuer must provide, in a timely manner, the following information: (1) whether the QPA for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount; (2) if a related service code was used to determine the QPA for a new service code, information to identify the related service code; (3) if the plan or issuer used an eligible database to determine the QPA, information to identify which database was used; and (4) if applicable, upon request, a statement that the plan's or issuer's

contracted rates include risk-sharing, bonus, or other incentive-based or retrospective payments or payment adjustments for covered items and services that were excluded for purposes of calculating the QPA.

The Departments assume that TPAs will provide this information on behalf of self-insured plans. In addition, the Departments assume that issuers and TPAs will automate the process of preparing and providing this information in a format similar to an explanation of benefits as part of the system to calculate the QPA. The cost to issuers and TPAs of making the changes to their IT systems is discussed previously in the RIA.

The Departments estimate that a total of 1,758 issuers and TPAs will incur burden to comply with this provision. Currently, 14 states have established some payment standards for services provided by nonparticipating providers or nonparticipating emergency facilities. Therefore, the Departments assume that issuers and TPAs will potentially need to calculate the QPA for two-thirds of the claims involving nonparticipating providers or nonparticipating emergency facilities.

In 2018, there were approximately 39,690,940 emergency department visits for patients with individual market or group health coverage.¹⁸³ The Departments estimate that approximately 18 percent of these visits¹⁸⁴ will include services provided by nonparticipating providers or nonparticipating emergency facilities and plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the specified information along with the initial payment or denial notice for approximately 4,786,727 claims annually from nonparticipating providers or nonparticipating emergency facilities for emergency department visits. In addition, in 2018, there were approximately 4,146,476

¹⁸³ Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits. <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide>.

¹⁸⁴ Estimate from Pollitz, K et al., Surprise Bills Vary by Diagnosis and Type of Admission, Peterson-KFF Health System tracker, December 9, 2019, <https://www.healthsystemtracker.org/brief/surprise-bills-vary-by-diagnosis-and-type-of-admission/>.

emergency department visits that resulted in hospital admission for patients with individual market or group health coverage. Using this as an estimate of post-stabilization services provided in emergency facilities, and assuming that in 16 percent of cases the patient is treated at a nonparticipating emergency facility or by a nonparticipating provider at a participating facility,¹⁸⁵ the Departments estimate that approximately 663,436 individuals will have the potential to be treated by a nonparticipating provider or facility. In the absence of data, the Departments assume that in 50 percent of cases services will be provided by nonparticipating providers without satisfying the notice and consent criteria in these interim final rules for reasons such as unforeseen, urgent medical needs and lack of participating providers in the facility. The Departments estimate that plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the required information along with the initial payment or denial notice for approximately 222,251 claims from nonparticipating providers or nonparticipating emergency facilities for post-stabilization services. Additionally, based on 2016 data, the Departments estimate that there will be 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures for individuals with group health coverage or individual market coverage.¹⁸⁶ The Departments assume that in 16 percent of cases the patient will have the potential to receive care from a nonparticipating provider at a participating facility, and that in approximately 5 percent of those cases services will be provided by nonparticipating providers without satisfying the notice and consent criteria in these interim final rules for reasons such as the services being ancillary services or related to unforeseen, urgent medical needs, and plans and issuers will need to calculate the QPA for two-thirds of such claims. Therefore, plans and issuers will be required to provide the required information along with the initial payment or denial notice for approximately 59,534 claims annually for non-

¹⁸⁵ Estimate from Pollitz, K et al., Surprise Bills Vary by Diagnosis and Type of Admission, Peterson-KFF Health System tracker, December 9, 2019, <https://www.healthsystemtracker.org/brief/surprise-bills-vary-by-diagnosis-and-type-of-admission/>.

¹⁸⁶ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

emergency services furnished by a nonparticipating provider at a participating health care facility. In total, plans and issuers will be required to provide documents related to QPAs along with the initial payment or denial of payment for approximately 5,068,512 claims annually from nonparticipating providers or facilities.

The Departments estimate that for each issuer or TPA it will take a medical secretary 10 minutes (at an hourly rate of \$37.50) to prepare the documentation and attach it to each payment or denial notice or explanation of benefits sent to the nonparticipating provider or facility. The Departments assume that this information will be sent electronically at minimal cost. The total annual burden for all issuers and TPAs to provide the QPA information and certification along with 5,068,512 payments or denial notices, is estimated to be approximately 844,752 hours, with an associated equivalent cost of approximately \$31.7 million.

The Departments assume that for the 5,068,512 QPA information sent to nonparticipating providers or nonparticipating emergency facilities, 50 percent will result in requests to provide additional information and plans and issuers will be required to send additional information to approximately 2,534,256 providers or facilities. The Departments estimate that it will take a medical secretary 15 minutes (at an hourly rate of \$37.50) to prepare the document and provide it to the provider or facility that requested it. The Departments assume that this information will be delivered electronically with minimal additional cost. The total estimated burden, for all issuers and TPAs, will be approximately 633,564 hours annually, with an associated equivalent cost of approximately \$23.8 million.

The total annual burden for all issuers and TPAs for providing the initial and additional information related to QPA will be 1,478,316 hours, with an equivalent cost of \$55,436,853. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 739,158 burden hours with an equivalent cost of approximately \$27,718,427. The Departments seek comment on these burden estimates.

TABLE 5: Annual Burden and Cost for Plans and Issuers to Provide Information Related to QPA to Nonparticipating Providers and Nonparticipating Emergency Facilities

	Estimated Number of Respondents	Estimated Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Cost
Initial information	879	2,534,256	0.167	422,376	\$15,839,100.93
Additional Information	879	1,267,128	0.25	316,782	\$11,879,325.70
Total	879	3,801,384		739,158	\$27,718,427.63

3. ICRs Regarding Audits of QPA (45 CFR 149.140(f))

The No Surprises Act provides that rulemaking must establish a process under which group health plans and health insurance issuers offering group or individual health insurance coverage are audited by the applicable Secretary or applicable state authority to ensure that such plans and coverage are in compliance with the requirement of applying a QPA and that the QPA applied satisfies the definition under the No Surprises Act with respect to the year involved.

These interim final rules include an audit provision establishing that the Departments' existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA consistent with these interim final rules.

HHS has primary enforcement authority over issuers (in a state if the Secretary of HHS makes a determination that a state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act) and non-federal governmental plans, such as those sponsored by state and local government employers and expects to conduct no more than 9 audits annually. Therefore, this collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

4. ICRs Regarding Disclosure for Self-Insured Plans Opting-in to State Law (45 CFR 149.30)

These interim final rules allow self-insured group health plans, including self-insured non-federal governmental plans, to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has

chosen to expand access to such plans, to satisfy their obligations under section 9816(a)-(d) of the Code, section 716(a)-(d) of ERISA, and section 2799A-1(a)-(d) of the PHS Act. A self-insured plan that has chosen to opt-in to a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted in to a specified state law, identify the relevant state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

Based on available data, HHS estimates that approximately 84 self-insured non-federal governmental plans in New Jersey, Nevada, Virginia and Washington¹⁸⁷ will opt-in and incur the one-time burden and cost to include the disclosure in their plan documents in 2022. It is estimated that for each plan an administrative assistant will spend 1 hour (at an hourly rate of \$38.86) and a compensation and benefits manager will spend 30 minutes (at an hourly rate of \$131.88) to prepare the disclosure. The estimated total burden for each plan will be 1.5 hours with an equivalent cost of approximately \$105. The estimated total annual burden for all 84 plans will be approximately 126 hours with an equivalent cost of approximately \$8,783. HHS estimates that there are approximately 11,956 policyholders in these plans that will be provided the disclosure. HHS assumes that only printing and material costs are associated with the disclosure requirement, because the notice can be incorporated into existing plan documents. HHS estimates that the disclosure will require one-half of a page, at a cost of \$0.05 per page for printing and materials, and 34 percent of plan documents will be delivered electronically at minimal cost.¹⁸⁸ Therefore, the cost to deliver 66 percent of these disclosures in print is estimated to be approximately \$197. The total one-time cost for all plans, incurred in 2022, is estimated to be approximately \$8,981.

¹⁸⁷ Based on data on self-insured plans that have opted in available at: <https://www.insurance.wa.gov/self-funded-group-health-plans>, <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>, <https://scc.virginia.gov/balancebilling>.

¹⁸⁸ 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>.

TABLE 6: One-time Burden and Cost to Provide Disclosure Regarding Opting in to State Law

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Labor Cost	Total Estimated Printing and Materials Cost	Total Estimated Cost
2022	84	84	1.5	126	\$8,783	\$197	\$8,981

5. ICRs Regarding Complaints Process for Surprise Medical Bills (45 CFR 149.150, 45 CFR 149.450)

The No Surprises Act directs the Departments to establish a process to receive complaints regarding violations of the application of the QPA requirements by group health plans and health insurance issuers offering group or individual health coverage under section 9816(a)(2)(B)(iv) of the Code, section 716(a)(2)(B)(iv) of ERISA, and section 2799A-1(a)(2)(B)(iv) of the PHS Act, and violations by health care provider, facilities, and providers of air ambulance services of the requirements under sections 2799B-1, 2799B-2, 2799B-3, and 2799B-5 of the PHS Act. The Departments are of the view that the complaints process should extend to all of the balance billing requirements and define a complainant as any individual, or their authorized representative, who files a complaint, as described and defined in these interim final rules. This regulatory action is taken as required by the No Surprises Act, which directs the Departments to create a process for balance billing complaints regarding plans and issuers, and directs HHS to create a process for balance billing complaints regarding providers and facilities.

HHS estimates that there will be, on average, 3,600 balance billing complaints against providers, facilities, providers of air ambulance services, plans, and issuers submitted annually. HHS estimates that it will take each complainant 30 minutes (at an hourly rate of \$54.14)¹⁸⁹ to collect all relevant documentation related to the alleged violation and to access and complete the

¹⁸⁹ The Departments use the average wage rate for all occupations.

provided complaint form, with an equivalent cost of approximately \$27. The total burden for all complainants is estimated to be 1,800 hours, with an equivalent annual cost of approximately \$97,452. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, approximately 900 burden hours with an equivalent cost of approximately \$48,726.

TABLE 7: Annual Burden and Costs for Complaints Related to Surprise Billing

Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Cost per Response	Total Annual Burden (Hours)	Total Estimated Cost
1,800	1,800	0.5	\$27.07	900	\$48,726

6. ICRs Regarding Notice of Right to Designate a Primary Care Provider (45

CFR 149.310(a)(4))

These interim final rules continue to require that if a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or coverage and their right to designate a primary care provider. For group health plans and group health insurance coverage, the notice must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or coverage. For individual health insurance coverage, the notice must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance. These interim final rules continue to include model language to satisfy the notice requirements. The No Surprises Act extends the applicability of the patient protections for choice of health care professionals to grandfathered health plans. The patient protections under section 2719A of the PHS Act apply to only non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. In contrast, the patient protections

under the No Surprises Act apply generally to all group health plans and group and individual health insurance coverage, including grandfathered health plans. Therefore, the requirements regarding patient protections for choice of health care professional under these interim final rules will newly apply to grandfathered health plans for plan years beginning on or after January 1, 2022.

In order to satisfy the patient protection disclosure requirement, state and local government plans and issuers in the individual market will need to notify policy holders of their plans' policy in regards to designating a primary care physician and for obstetrical or gynecological visits and will incur a one-time burden and cost to incorporate the notice into plan documents. Non-federal governmental plans and individual market plans that are currently not grandfathered have already incurred the one-time cost to prepare and incorporate this notice in their existing plan documents.

There are an estimated 90,126 non-federal governmental employers offering health plans to employees and 388 health insurance issuers in the individual market. HHS estimates that there are approximately 14,417 grandfathered non-federal government employer-sponsored plans and approximately 837,543 grandfathered individual market policies, with approximately 6,055 grandfathered non-federal governmental plans offering HMO and point-of-service (POS) options.¹⁹⁰ HHS assumes that all individual market issuers offer at least one HMO, exclusive provider organization (EPO) or POS options.

It is estimated that in 2022, 5,450 grandfathered non-federal governmental plans and individual market policies will be subject to this notice requirement. While not all HMO, EPO, and POS options require the designation of a primary care physician or a prior authorization or referral before an OB/GYN visit, HHS is unable to estimate this number. Therefore, this estimate should be considered an overestimate of the number of affected entities.

¹⁹⁰ According to 2020 Kaiser/HRET survey of Employer Health Benefits, 11 percent of employers offer a health maintenance organization (HMO) option and that 31 percent of employers offer a point-of-service (POS) option. Available at <https://www.kff.org/health-costs/report/2020-employer-health-benefits-survey/>.

These interim final rules continue to provide model language for the notice. It is estimated that each plan or issuer will require a compensation and benefits manager (at an hourly rate of \$131.88) to spend 10 minutes customizing the model notice to fit the plan's specifications. Each plan or issuer will also require clerical staff (at an hourly rate of \$38.86) to spend 5 minutes adding the notice to the plan's documents. The estimated total burden for each plan or issuer will be 0.25 hours with an equivalent cost of approximately \$25. In 2022, the estimated total annual burden for all 5,450 plans and issuers will be approximately 1,362 hours with an equivalent cost of approximately \$137,430. There will be no additional burden and cost in 2023 to prepare the notice, since all plans and issuers will have incurred the burden and cost by 2022.

HHS estimates that there are approximately 1.8 million non-federal governmental plan policyholders in grandfathered plans, with an estimated 413,976 policyholders enrolled in grandfathered HMO and POS plans options.¹⁹¹ In addition, there are an estimated 837,543 policyholders with grandfathered individual market plans. It is estimated that approximately 75 percent of individual market enrollees are enrolled in HMO, EPO, and POS options.¹⁹² Therefore, an estimated 627,146 policyholders in the individual market have grandfathered plans with HMO, EPO, and POS options. It is estimated that approximately 937,010 policyholders will remain in grandfathered non-federal government employer sponsored and individual market plans with HMO, EPO, and POS options in 2022 and will receive the required notice for the first time in 2022. HHS assumes that only printing and material costs are associated with the disclosure requirement, because the notice can be incorporated into existing plan documents. HHS estimates that the notice will require one-half of a page, at a cost of \$0.05 per page for printing and materials, and 34 percent of the notices will be delivered electronically at minimal

¹⁹¹ According to the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits, 12 percent of covered workers in non-federal government plans have an HMO option and that 11 percent of covered workers have a POS option.

¹⁹² Estimate based of data reported in Unified Review Template Submissions for 2018 plan. Rate review data available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/ratereview.html>.

cost.¹⁹³ Therefore, the cost to deliver 66 percent of these notices in print is estimated to be approximately \$15,461.¹⁹⁴

TABLE 8 One-time Burden and Cost to Provide Notice of Right to Designate a Primary Care Provider

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Total Annual Burden (Hours)	Total Estimated Labor Cost	Total Estimated Printing and Materials Cost	Total Estimated Cost
2022	5,450	5,450	0.25	1,362	\$137,430	\$15,461	\$152,891

HHS will revise the burden currently approved under OMB Control Number 0938-1094, (Notice of Rescission of Coverage and Disclosure Requirements for Patient Protection under the Affordable Care Act, CMS-10330, expiration: July 31, 2022) to account for this burden.

7. ICRs Regarding Notice and Consent to Waive Balance Billing Protections, Retention of Certain Documents, and Notice to Plan or Issuer (45 CFR 149.410(b)-(e), 45 CFR 149.420(c) - (i))

The No Surprises Act and these interim final rules require that a plan or issuer providing coverage of emergency services do so without the individual or the health care provider having to obtain prior authorization and without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility with respect to the services (regardless of the department of the hospital in which such items and services are furnished). Emergency services include any additional items and services that are covered under a plan or coverage after a participant, beneficiary, or enrollee is stabilized (referred to as post-stabilization services) unless certain notice and consent requirements are met. The No Surprises Act and these interim final rules further apply surprise billing protections in

¹⁹³ 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>.

¹⁹⁴ 937,010 notices x 66% = 618,427 notices printed x \$0.05 per page x 1/2 pages per notice = approximately \$15,461.

the case of non-emergency services furnished by nonparticipating providers during a visit by a participant, beneficiary, or enrollee at participating health care facilities unless notice and consent as specified in these interim final rules have been met. The requirements related to the notice and consent, applicable exceptions, and timing are set forth in section 2799B-2 of the PHS Act, and implemented at 45 CFR 149.410 and 45 CFR 149.420 of these interim final rules.

In order to meet the notice and consent requirements of these interim final rules, nonparticipating providers and nonparticipating emergency facilities must provide the participant, beneficiary, or enrollee with a notice, meet certain timing requirements, and obtain consent from the participant, beneficiary, or enrollee as described in 45 CFR 149.420 and these interim final rules. The provided notice must: (1) state the health care provider or facility is a nonparticipating provider or facility; (2) include the good faith estimate of what the individual may be charged, including any item or service that is reasonably expected to be provided in conjunction with such items and services; (3) provide information about whether prior authorization or other care management limitations may be required; and (4) clearly state that consent to receive such items or services is optional and that the participant, beneficiary, or enrollee may instead seek care from an available participating provider, in which case the individual's cost-sharing responsibility would be at the in-network level. In cases where post-stabilization services are furnished by a nonparticipating provider at a participating emergency facility, the notice must also include a list of participating providers at the participating emergency facility who are able to furnish the items or services involved and inform the individual that they may be referred, at their option, to such a participating provider.

Additionally, a nonparticipating provider or nonparticipating emergency facility must provide the participant, beneficiary, or enrollee, or such individual's authorized representative, with the notice and consent documents in any of the 15 most common languages in the state, or a geographic region that reasonably reflects the geographic region served by the applicable facility. If the individual's preferred language is not among the 15 most common languages

made available or the individual cannot understand the language in which the notice and consent document are provided the individual must be provided with a qualified interpreter.

In addition to providing the required notice and consent, nonparticipating emergency facilities, participating health care facilities, and nonparticipating providers are obligated to retain written notice and consent documents for at least a 7-year period after the date on which the item or service in question was furnished. Where the notice and consent requirements described in this interim final rule have been met, the nonparticipating provider, the participating health care facility on behalf of the nonparticipating provider, or the nonparticipating emergency facility, as applicable, must timely notify the plan or issuer, respectively, that the notice and consent criteria have been met, and if applicable, provide to the plan or issuer a copy of the signed notice and consent documents. In instances where, to the extent permitted by these rules, the nonparticipating provider bills the participant, beneficiary, or enrollee directly, the provider may satisfy the requirement to notify the plan or issuer by including the notice and consent documents with the bill to the participant, beneficiary, or enrollee. In addition, for items and services furnished by a nonparticipating provider at a participating health care facility, the provider (or the participating facility on behalf of the provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility.

In order to meet the notice and consent requirements of the statute and these interim final rules, nonparticipating providers and nonparticipating emergency facilities must provide the participant, beneficiary, or enrollee with a notice. HHS is specifying in guidance mandatory notice and consent forms that will require customization by the provider or facility.

HHS assumes that emergency facilities and health care facilities will provide the notice and obtain consent on behalf of nonparticipating providers, retain records and notify plans and issuers. HHS estimates that a total of 17,467 health care facilities and emergency departments (including 475 hospital-affiliated satellite and 270 independent freestanding emergency departments) will be subject to these requirements. HHS assumes that for hospital-affiliated

satellite freestanding emergency departments, the notice and consent will be developed by the parent hospital. Therefore, the burden to develop the notice and consent documents will be incurred by 16,992 emergency facilities and health care facilities. HHS estimates that for each facility it will take a lawyer 1 hour (at an hourly rate of \$143.18) to read and understand the notice and consent forms and make any required and applicable alteration, an administrative assistant half an hour (at an hourly rate of \$38.86) to make any alterations to the provided notice and consent documents and prepare the final documentation, a computer programmer 1 hour (at an hourly rate of \$91.96) to digitize and post on a shared network server or push to networked computers fillable versions of the notice and consent documents, and a Computer and Information Systems Manager half an hour (at an hourly rate of \$155.52) to verify accessibility to, and ensure functionality of, the notice and consent documents. HHS also estimates each facility will incur an additional cost of approximately \$1,000 (at \$500 per document) to contract with an outside firm to translate the notice and consent documents into the 15 most common languages in the state or a geographic region that reasonably reflects the geographic region served by the applicable facility. HHS estimates the one-time first-year burden, to be incurred in 2021, to make alterations, prepare the final versions, translate and make accessible to the providers within the facility the notice and consent documentation, for each facility will be approximately 3 hours, with an associated equivalent cost of approximately \$1,332. For all 16,992 emergency facilities and health care facilities, HHS estimates a total one-time first-year burden of 50,976 hours, with an associated equivalent cost of approximately \$22.6 million.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to post-stabilization services, when emergency services are provided by nonparticipating providers or nonparticipating emergency facilities, the provider or facility must provide the participant, beneficiary, or enrollee with a notice and obtain consent to be treated by the nonparticipating emergency facility or nonparticipating provider. HHS estimates there are approximately 5,533 emergency departments (including hospital-affiliated satellite and independent freestanding

emergency departments)¹⁹⁵ that could be subject to the notice and consent requirements in these interim final rules and will incur ongoing annual costs and burdens, beginning in 2022. In 2018, there were approximately 4,146,476 emergency department visits that resulted in hospital admission for patients with individual market or group health coverage.¹⁹⁶ Using this as an estimate of post-stabilization services provided in emergency facilities, and assuming that in 16 percent of cases the patient is treated at a nonparticipating emergency facility or by a nonparticipating provider at a participating facility, HHS estimates that approximately 663,436 individuals will be provided with a notice and consent document for post-stabilization services. HHS anticipates that the notice and consent will be used infrequently for post-stabilization services, so this estimate is an upper bound. HHS estimates it will take a medical secretary 2 hours (at an hourly rate of \$37.50) to customize the required notice and consent documents, generate a list of participating providers, provide and explain the documents to the individual (or authorized representative), answer questions, and obtain the signed consent if the individual agrees, provide the signed documents on paper or, as practicable, electronically, as selected by the individual, and retain the documentation as required by these interim final rules. The total burden for providing the notice and consent documents to individuals at all emergency facilities will be 1,326,872 hours with an equivalent cost of approximately \$49.8 million. HHS assumes that these documents will be provided directly to each affected individual (or authorized representative) in paper format and will be 4 pages (2 pages printed double-sided) on average. Assuming a cost of \$0.10 (at \$0.05 per page for printing and material cost) for each notice and consent document, the total printing and material costs for all notices will be approximately \$66,344. The total ongoing cost for all emergency facilities will be approximately \$49.8 million annually. HHS assumes that nonparticipating providers and nonparticipating emergency facilities

¹⁹⁵ Emergency Medicine Network, 2018 National Emergency Department Inventory – USA. Available at <https://www.emnet-usa.org/research/studies/nedi/nedi2018/>.

¹⁹⁶ Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits. Available at <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsEDServlet?measure1=01&characteristic1=14&measure2=&characteristic2=11&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide>.

will notify the plan or issuer and provide a copy of the signed notice and consent documents along with the claim form electronically at minimal cost.

HHS estimates that each individual that receives notice and consent from an emergency facility will require, on average, 45 minutes (at an hourly rate of \$54.14) to read and understand and sign the required notice and consent documents, with a total cost of approximately \$41. For all 663,436 individuals that could potentially receive the notice and consent documents, HHS estimates a total annual burden of 497,577 hours, with an associated total annual cost of approximately \$26.9 million.

In order to meet the notice and consent requirements of 45 CFR 149.420 with respect to non-emergency services furnished by a nonparticipating provider at a participating health care facility, if an individual schedules an appointment for such items or services at least 72 hours before the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, no later than 72 hours before the date of the appointment. If an individual schedules an appointment for such items or services within 72 hours of the date of the appointment, the provider or facility must provide the notice to the individual, or their authorized representative, on the day that the appointment is made. In the situation where an individual is provided the notice on the same day that the items or services are furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements applies.

HHS estimates there are approximately 16,722 health care facilities that will be subject to the notice requirement described in these interim final rules and will incur ongoing annual costs and burdens beginning in 2022. Based on 2016 data, HHS estimates that there will be 11,107,056 visits to health care facilities annually for surgical and non-surgical procedures for individuals with group health coverage or individual market coverage¹⁹⁷ and that approximately 16 percent

¹⁹⁷ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

of those visits will involve a nonparticipating provider.¹⁹⁸ This estimate is a lower bound since it is based on the number of postoperative office visits and potentially excludes situations where such visits were not needed or such follow-up was conducted at a different setting. HHS therefore estimates that approximately 1,777,129 individuals could potentially face balance billing and will be subject to the notice requirements of these interim final rules. With respect to non-emergency services furnished by a nonparticipating provider at a participating health care facility, HHS estimates it will take a medical secretary 1 hour (at an hourly rate of \$37.50) to customize the required notice, generate a list of participating providers, provide the document via e-mail or mail, as selected by the individual, and answer any questions. For all health care facilities, HHS estimates a total annual ongoing annual burden of approximately 1,777,129 hours, with an associated annual cost of approximately \$66.6 million. HHS estimates that approximately 66 percent of the notices will be mailed to individuals (34 percent sent electronically) at a cost of \$0.65 (at \$0.05 per page for printing and material cost and \$0.55 postage).¹⁹⁹ Assuming minimal cost for electronic delivery, the total cost of printing and mailing the notice and consent documents will be approximately \$762,388 annually. The total ongoing cost for all health care facilities will be approximately \$67.4 million annually.

HHS estimates that each individual that receives the notice will require, on average, 45 minutes (at an hourly rate of \$54.14) to read and understand the required notice, with a total cost of \$41. For all 1,777,129 individuals that could receive the notice document, HHS estimates a total annual burden of 1,332,847 hours, with an associated total annual cost of \$72.2 million. HHS assumes that nonparticipating providers (or the participating facilities on behalf of the providers) will notify the plan or issuer and provide a copy of the signed notice and consent documents along with the claim from the participating facility electronically at minimal cost.

¹⁹⁸ Estimated based on information provided by KFF. Available at: <https://www.kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills/>.

¹⁹⁹ 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>.

For all emergency and health care facilities, the total ongoing burden will be 3,104,001 hours annually and the total cost, including printing and materials cost, will be approximately \$117,228,780 annually starting in 2022. For all consumers, the total annual burden to read and understand the notice will be 1,830,424 hours with an equivalent cost of \$99,099,147 starting in 2022.

TABLE 9: One-time and Annual Burden and Cost for Emergency Departments and Facilities Related to Notice and Consent

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Translating, Printing and Materials Cost	Total Estimated Cost
2021	16,992	16,992	50,976	\$5,646,951	\$16,992,000	\$22,638,951
2022	17,467	2,440,565	3,104,001	\$116,400,048	\$828,732	\$117,228,780
2023	17,467	2,440,565	3,104,001	\$116,400,048	\$828,732 \$183,634	\$117,228,780
3 Year Average	17,309	1,632,707	2,086,326	\$79,482,349	\$6,216,488	\$85,698,837

TABLE 10: Annual Burden and Cost for Individuals Related to Notice and Consent Starting in 2022

Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Cost
2,440,565	2,440,565	1,830,424	\$99,099,147	\$99,099,147

8. ICRs Regarding Provider Disclosure on Patient Protections Against Balance Billing (45 CFR 149.430)

Section 2799B-3 of the PHS Act, as added by the No Surprises Act and codified at 45 CFR 149.430, requires providers and facilities to provide disclosures regarding patient protections against balance billing. Specifically, health care providers and facilities (including an emergency department of a hospital or independent freestanding emergency department) are required to make publicly available, post on a public website of the provider or facility, and provide to participants, beneficiaries, and enrollees a one-page notice about surprise billing protections, which must include information about any applicable state requirements, and about how to contact appropriate state and federal agencies if the individual believes the provider or

facility has violated the balance billing rules. The required notice must include clear and understandable language that explains the requirements and prohibitions relating to the prohibitions on balance billing in cases of emergency services and in cases of non-emergency services performed by a nonparticipating provider at certain participating facilities, explain any other applicable state laws, and provide contact information for the appropriate state and federal agencies that an individual may contact if they believe the provider or facility has violated a requirement described in the notice.

Health care providers and facilities are required to publicly post and make the disclosure publicly available through a public website accessible free of charge that is easily accessible, without barriers, including via search engines, and that ensures that the information is accessible to the general public. HHS assumes that providers and facilities will enter into agreements for the facilities to provide the disclosure on behalf of the providers and that the required language and information will be developed, posted within the facility, and posted on a public website by the facility. This will ameliorate the burden and cost for the individual provider. Many facilities and providers will be able to enter into an agreement at minimal cost if they renew their contracts prior to 2022. For each facility whose contracts with providers are not due to be renewed before 2022, the burden to enter into agreements related to this disclosure will vary based on the number of providers that practice within the facility. HHS estimates that for each facility, on average, it will take a lawyer 2 hours (at an hourly rate of \$143.18) to draft an agreement and an administrative assistant 2 hours (at an hourly rate of \$38.86) to provide electronic copies to all providers to sign. The total burden for all 17,467 facilities will be 69,868 hours with an equivalent cost of approximately \$6,359,385, to be incurred as one-time costs in 2021. HHS is unable to estimate how many providers will incur burden to sign the agreement, but anticipates that the burden to sign each agreement will be minimal. In future years, this agreement can be included in the contract between the facilities and providers at no additional cost.

HHS estimates a total of 17,467 health care facilities (including 475 hospital-affiliated satellite and 270 independent freestanding emergency departments) will incur burden and costs to comply with this provision. HHS assumes that for hospital-affiliated satellite freestanding emergency departments, the disclosure will be developed by the parent hospital. HHS estimates that for each facility, on average, it will take a lawyer 2 hours (at an hourly rate of \$143.18) to read and understand the provided notice and draft any additional, clear, and understandable language as may be needed, an administrative assistant 30 minutes (at an hourly rate of \$38.86) to prepare the final document for distribution and make the information publicly available within the facility, and a computer programmer 1 hour (at an hourly rate of \$91.96) to post the information on a separate or existing webpage, in a searchable manner, and to make the content available in an easily downloadable format. The burden will be higher for facilities in states with state laws or All-Payer Model Agreements, but lower for facilities in states without any state laws. HHS assumes that each facility will post a single page document in at least two prominent locations, such as where individuals schedule care, check-in for appointments, or pay bills, and estimates that each facility will incur a printing cost of \$0.10 (at \$0.05 per page for printing and materials) in order to post the required disclosure information prominently at each health care facility. HHS anticipates that hospitals will post 6 notices on average, and incur an additional cost of \$0.20 each. In addition, HHS assumes that each of the 475 hospital-affiliated satellite freestanding emergency departments will post two notices on average and incur a cost of \$0.10 each. HHS estimates the one-time burden, to be incurred in 2021, to develop, prepare, and post the required disclosure information, for each facility will be approximately 3.5 hours, with an associated equivalent cost of approximately \$398. For all facilities, HHS estimates a total one-time burden of 59,472 hours, with an associated cost of approximately \$6.8 million, including materials and printing costs. HHS recognizes that there are some small providers and facilities that do not maintain or provide a publicly available website. Such entities are not required to

make a disclosure on a public website. Therefore, HHS considers the estimate to be a high-end estimate.

HHS encourages states to develop language to assist providers and facilities in fulfilling this disclosure requirement. There are currently 33 states that have enacted laws to provide some protection to consumers for surprise billing. Some or all of these states may choose to develop model language. HHS assumes that it will take a lawyer 2 hours (at an hourly rate of \$143.18) and an administrative assistant 1 hour (at an hourly rate of \$38.86) to develop and amend the model language. The total one-time burden, to be incurred in 2021, for each state will be 3 hours with an equivalent cost of approximately \$325. For all 33 states, HHS estimates the total one-time burden will be 99 hours with an equivalent cost of approximately \$10,732.

In addition to requiring providers and facilities to publicly post and make the required disclosure publicly available through a public website, providers and facilities are required to provide individuals the required disclosure information in a one-page notice. The required notice must be provided in-person, through the mail or via email, as selected by the participant, beneficiary, or enrollee no later than the date on which the health care provider or health care facility requests payment from the individual (including requests for copayment made at the time of a visit to the provider or facility), or with respect to individual from whom the health care facility or health care provider does not request payment, no later than the date on which the health care provider or health care facility submits a claim to the group health plan or health insurance issuer. HHS assumes that, in order to reduce burden and costs, facilities will choose to provide the required disclosure to the individual (or their selected representative) at the time the individual is processed for any visit, upon check-in, or when other standard disclosures are shared with individuals with minimal additional burden. HHS estimates that there will be approximately 39,690,940 emergency department visits²⁰⁰ and 11,107,056 visits to health care

²⁰⁰ Agency for Healthcare Research and Quality, HCUP Fast Stats – Trends in Emergency Department Visits.

facilities annually for surgical and non-surgical procedures²⁰¹ for individuals with group health coverage or individual market coverage. This is a lower bound for the number of patients who will receive the disclosure since HHS lacks comprehensive data on patients who receive services on all health care facilities. In order to provide the required disclosure to individuals each facility will incur a cost of approximately \$0.05 for printing and materials for each disclosure. HHS assumes that this disclosure will be provided along with other forms and notices usually provided to individuals without incurring significant labor cost. For all facilities, HHS estimates a total annual ongoing annual cost of \$2.5 million, starting in 2022. HHS recognizes that the number of notices provided by each facility will vary depending on the number of annual visits and that some facilities could incur higher costs to provide the disclosure while others could incur lower costs. HHS assumes that all disclosures will be provided in-person; however, HHS acknowledges that some individuals will choose to have this notice provided to them via email, at a minimal cost to the facility, and others may choose to receive the disclosure via mail, in which case the facility will incur additional postage costs.

HHS seeks comment on these burden estimates. Specifically, HHS seeks comment on the costs and burdens associated with posting the required information on a public website. HHS also seeks comment on the number of facilities that will be affected by these requirements and the number of individuals that would be required to receive the required notice.

TABLE 11: One-time Burden and Costs Related to Agreements between Facilities and Providers

Year	Estimated Number of Respondents	Estimated Number of Responses	Burden Per Response (Hours)	Cost per Response	Total Annual Burden (Hours)	Total Estimated Cost
2021	17,467	17,467	4	\$364.08	69,868	\$6,359,385

²⁰¹ Estimates based on data on postoperative office visits. Centers for Disease Control, National Ambulatory Medical Care Survey: 2016 National Summary Tables. Available at <https://www.cdc.gov/nchs/fastats/physician-visits.htm>.

²⁰¹ Estimated based on information provided by KFF. Available at: <https://www.kff.org/health-costs/poll-finding/data-note-public-worries-about-and-experience-with-surprise-medical-bills/>.

TABLE 12: One-time and Annual Burden and Cost for Facilities to Provide Disclosure on Patient Protections against Balance Billing

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Printing and Materials Cost	Total Estimated Cost
2021	17,467	17,467	59,472	\$6,758,568	\$2,965	\$6,761,533
2022	17,467	50,797,996	0	\$0	\$2,539,900	\$2,539,900
2023	17,467	50,797,996	0	\$0	\$2,539,900	\$2,539,900
3 Year Average	17,467	33,871,153	19,824	\$2,252,856	\$1,694,255	\$3,947,111

TABLE 13: One-time Burden and Cost for States to Develop State Specific Language for Facilities to Provide Disclosure on Patient Protections against Balance Billing

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost
2021	33	33	99	\$10,732.26

9. ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing

Section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act require plans and issuers to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act apply, information in plain language on the provisions in these sections, and sections 2799B-1 and 2799B-2 of the PHS Act, and other applicable state laws on out-of-network balance billing, and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing.

The Departments assume that plans and issuers will use the model notice developed by HHS, and that TPAs will develop the notice for self-insured plans. The Departments estimate that on average for each plan or issuer it will take a lawyer 2 hours (at an hourly rate of \$143.18) to read and understand the provided notice and draft any additional, clear, and understandable

language as may be needed, an administrative assistant 30 minutes (at an hourly rate of \$38.86) to prepare the final document for distribution and make the information publicly available within the facility, and a computer programmer 1 hour (at an hourly rate of \$91.96) to post the information on a separate or existing webpage, in a searchable manner, and to make the content available in an easily downloadable format. The total burden for an individual plan or issuer will be 3.5 hours with an equivalent cost of approximately \$398. The burden will be higher for issuers and TPAs in states with applicable state laws or All-Payer Model Agreements, but lower for issuers and TPAs in states without any applicable state laws. The Departments estimate that there are 1,553 issuers and 205 TPAs. The total burden for all issuers and TPAs will be 6,153 hours with an equivalent cost of \$699,245, to be incurred as a one-time cost in 2021. As DOL, the Treasury Department, and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 3,077 hours with an equivalent cost of approximately \$349,622.

The Departments assume that plans and issuers will also include the disclosure along with the explanation of benefits at no additional cost. Under the same assumptions used to estimate the number of disclosures provided by nonparticipating facilities and nonparticipating providers, the Departments estimate that issuers and TPAs will include the disclosure to approximately 39,690,940 individuals who receive services at emergency facilities and 11,107,056 individuals who received non-emergency services at health care facilities, for a total of 50,797,996 disclosures. The Departments assume that 66 percent of these notices will be provided by mail and the cost of printing is \$0.05 per page.²⁰² Therefore, the total printing and materials cost for sending 33,526,677 notices by mail will be \$1,676,334 annually, starting in 2022. The Departments assume that for the disclosures sent by mail, it will take an administrative assistant 1 minute (at an hourly rate of \$38.86) to print and enclose the notice with the explanation of benefits. The disclosures sent electronically can be sent at minimal cost. The

²⁰² 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>.

total burden for all issuers and TPAs is estimated to be 558,778 hours with an equivalent cost of \$21,714,111. There will be no additional mailing costs, since the disclosure will be enclosed with the explanation of benefits. The total annual cost to all issuers and TPAs for sending the notices is estimated to be approximately \$23,390,445 starting in 2022. As DOL, the Treasury Department and HHS share jurisdiction, HHS will account for 50 percent of the burden, or approximately 279,389 hours, with an equivalent cost of \$10,857,056, and printing and materials cost of \$838,167, for a total annual cost of \$11,695,223 starting in 2022.

TABLE 14: One-time and Annual Burden and Cost for Plans and Issuers to Provide Disclosure on Patient Protections against Balance Billing

Year	Estimated Number of Respondents	Estimated Number of Responses	Total Annual Burden (hours)	Total Estimated Labor Cost	Total Estimated Printing and Materials Cost	Total Estimated Cost
2021	879	879	3,077	\$349,622	0	\$349,622
2022	879	25,398,998	279,389	\$10,857,056	\$838,167	\$11,695,223
2023	879	25,398,998	279,389	\$10,857,056	\$838,167	\$11,695,223
3 year Average	879	16,932,958	187,285	\$7,354,578	\$558,778	\$7,913,356

10. Summary of Annual Burden Estimates for Information Collection Requirements

TABLE 15: Annual Recordkeeping and Reporting Requirements

Regulation Section	OMB Control Number	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 149.140(d)	0938-NEW	879	3,801,384	0.19	739,158	\$37.50	\$27,718,427	0	\$27,718,427
45 CFR 149.30	0938-NEW	84	84	1.50	126	\$69.87	\$8,783	\$197	\$8,981
45 CFR 149.150, 149.450	0938-NEW	1,800	1,800	0.5	900	\$54.14	\$48,726	0	\$48,726
45 CFR 149.310(a)(4)	0938-1094	5,450	5,450	0.25	1362	\$100.87	\$137,430	\$15,461	\$152,891
45 CFR 149.410(b)-(e), 149.420(c) - (i) – Facilities and Providers	0938-NEW	17,309	1,632,707	1.28	2,086,326	\$38.10	\$79,482,349	\$6,216,488	\$85,698,837
45 CFR 149.410(b)-(e), 149.420(c) - (i) – Consumers	0938-NEW	2,440,565	2,440,565	0.75	1,830,424	\$54.14	\$99,099,147	0	\$99,099,147

Regulation Section	OMB Control Number	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 149.430 – Facilities and Providers	0938-NEW	17,467	33,871,153	3.5*	19,824	\$113.67*	\$2,252,856	\$1,694,255	\$3,947,111
45 CFR 149.430 – Facility and Provider agreements	0938-NEW	17,467	17,467	4	69,868	\$91.02	\$6,359,385	0	\$6,359,385
45 CFR 149.430 – States	0938-NEW	33	33	3	99	\$108.41	\$10,732	0	\$10,732
Section 2799A-5(c) of the PHS Act	0938-NEW	879	16,932,958	0.01	187,285	\$39.27	\$7,354,578	558,778	\$7,913,356
Total		2,501,933	58,703,602		4,935,372		\$222,472,414	\$8,485,179	\$230,957,592

*: Estimate based on burden incurred in first year only.

11. Submission of PRA-Related Comments

HHS has submitted a copy of this final rule to OMB for its review of the rule’s information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule (CMS-9909-IFC), please visit the CMS Web site at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410–786–1326.

E. Paperwork Reduction Act – Department of Labor and Department of the Treasury

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 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:

1. ICRs Regarding Notice of Right to Designate a Primary Care Provider (26 CFR 54.9822-1T, 29 CFR 2590.722)

These interim final rules require that if a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or coverage and their right to designate a primary care provider. For group health plans and group health insurance coverage, the notice must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or coverage. For individual health insurance coverage, the notice must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance. These interim final rules include model language to satisfy the notice requirements. The No Surprises Act extends the applicability of the patient protections for choice of health care professionals. The patient protections under section 2719A of the PHS Act apply to only non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. In contrast, the patient protections under the No Surprises Act apply generally to all group health plans and group and individual health insurance coverage, including grandfathered health plans. Therefore, the requirements regarding patient protections for choice of health care professional under these interim final rules will newly apply to grandfathered health plans for plan years beginning on or after January 1, 2022.

DOL estimates that there are 2.5 million ERISA-covered plans. Data obtained from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 16 percent of firms offering health benefits offer at least one grandfathered health plan. DOL estimates that five

percent of plans will relinquish their grandfathered status in 2021. The data from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits also finds that 11 percent of plans have an HMO option and that 31 percent of plans offer a POS option. Thus, DOL estimates that in 2022, 161,148 grandfathered plans will be subject to this notice requirement.²⁰³

While not all HMO and POS options require the designation of a primary care physician or a prior authorization or referral before an OB/GYN visit, DOL is unable to estimate this number. Therefore, these estimates should be considered an overestimate of the number of affected entities.

Each of the plans will require a compensation and benefits manager to spend 10 minutes individualizing the model notice to fit the plan's specifications at an hourly rate of \$134.21.²⁰⁴ In 2022, this results in 26,858 hours of burden at an equivalent cost of \$3,604,602.

Each plan will also require clerical staff to spend 5 minutes adding the notice to the plan's documents at an hourly rate of \$55.14. In 2022, this results in 13,429 hours of burden at an equivalent cost of \$740,473.

Thus, the total hour burden associated with this ICR is 40,287 hours at an equivalent cost of \$4,345,075. DOL shares this burden equally with the Department of the Treasury. Therefore, the total hour burden for DOL and the Treasury Department is each approximately 20,143 hours at an equivalent cost of \$2,172,537.

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Departments estimate that the

²⁰³ 2.5 million ERISA-covered plans x 16% grandfathered plans x (100% minus 5% newly non-grandfathered plans) x (11% HMOs + 31% POSs) = 161,148 affected plans.

²⁰⁴ For more information on how the Department estimates labor costs see: <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebbsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>

notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 58.2 percent of the notices will be delivered electronically.²⁰⁵

DOL estimates that there are 62.6 million ERISA-covered policyholders. Data obtained from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 14 percent of covered workers are enrolled in a grandfathered plan. DOL estimates that 5 percent of plans would relinquish their grandfathered status annually in 2021. The data from the 2020 Kaiser/HRET Survey of Employer Sponsored Health Benefits also finds that 13 percent of covered workers have an HMO option and that 8 percent of covered workers have a POS option. DOL estimates that plans will produce 730,346 notices in 2022.²⁰⁶ This results in a cost burden of approximately \$18,259 in 2022.²⁰⁷ DOL shares this burden equally with the Department of the Treasury. Therefore, the total cost burden for DOL is approximately \$9,129 and the total cost burden for the Treasury Department is \$9,129. The summary of burden for this information collection has also been provided below.

Summary of Burden

Type of Review: Revised Collection.

Agency: DOL–EBSA, Treasury-IRS

Title: Affordable Care Act Patient Protection Notice

OMB Numbers: 1210-0142, 1545–2181

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

²⁰⁵ According to data from the National Telecommunications and Information Agency (NTIA), 40.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7 percent receiving electronic disclosure outside of work). Combining the 33.6 percent who receive electronic disclosure at work with the 24.7 percent who receive electronic disclosure outside of work produces a total of 58.2 percent who will receive electronic disclosure overall.

²⁰⁶ 2022: 62.6 million ERISA-covered policyholders x 14% of covered employees in grandfathered plans x (100% minus 5% newly non-grandfathered plans) x (13% in HMOs + 8% in POSs) *41.8% = 730,346 notices

²⁰⁷ 2022: \$0.05 per page*1/2 pages per notice * 730,346 notices = \$18,259

Total Respondents: 161,148

Total Responses: 730,346

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 40,287 (DOL- 20,143; Treasury- 20,143)

Estimated Total Annual Burden Cost: \$18,259 (DOL- \$9,129; Treasury- \$9,129)

2. ICRs Regarding Information to be Shared about QPA (26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d))

These interim final rules require plans and issuers to provide certain information to nonparticipating providers or nonparticipating emergency facilities in cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility is the QPA. Specifically, plans and issuers must provide the following information to providers (including air ambulance providers) and facilities, when making an initial payment or notice of denial of payment: (i) the QPA for each item or service involved; and (ii) a statement certifying that the plan or issuer has determined that the QPA applies for the purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and that each QPA was determined in compliance with 26 CFR 54.9816-6T(d), 29 CFR 2590.716-6, or 45 CFR 149.140, as applicable. Additionally, upon request of the provider or facility, the plan or issuer must provide in a timely manner the following information: (i) whether the QPA for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount; (ii) if applicable, information to identify which database was used to determine the QPA; and (iii) if applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, or incentive based payments for covered items and services (as applicable) that were excluded for purposes of calculating the QPA.

As discussed earlier in HHS' PRA section, the total annual burden for all issuers and TPAs for providing the initial and additional information related to QPA will be 1,478,316 hours, with an equivalent cost of \$55,436,853. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. Thus, HHS will account for approximately 739,158 burden hours with an equivalent cost of approximately \$27,718,427. DOL and the Treasury Department will each account for 369,579 burden hours with an equivalent cost of approximately \$13,859,214.

3. ICRs Regarding Complaints Process for Surprise Medical Bills (26 CFR 54.9816-7T, 29 CFR 2590.716-7)

The No Surprises Act directs the Departments to establish a process to receive complaints regarding violations of the application of the QPA by group health plans and health insurance issuers offering group or individual health coverage, and violations by health care providers, facilities, and providers of air ambulance services of the requirements under sections 2799B-2 and 2799B-3 of the PHS Act. The Departments define a complainant as any individual, or their authorized representative, who files a complaint, as described and defined in these interim final rules. This regulatory action is taken as required by the No Surprises Act, which directs the Departments to create a process for balance billing complaints regarding plans and issuers, and directs HHS to create a process for balance billing complaints regarding providers and facilities.

As discussed earlier in HHS' PRA section, the total burden for all complainants is estimated to be 1,800 hours, with an equivalent annual cost of approximately \$97,452. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. HHS will account for approximately 900 burden hours with an equivalent cost of approximately \$48,726.

DOL and the Treasury Department will each account for approximately 450 burden hours with an equivalent cost of approximately \$24,363.

4. ICRs Regarding Opt-In State Balance Bill Process (26 CFR 54.9816-3T, 29 CFR 2590.716-3)

The interim final rules allow plans to voluntarily opt in to state law that provides for a method for determining the cost-sharing amount or total amount payable under such a plan, where a state has chosen to expand access to such plans, to satisfy their obligations under section 9816(a)-(d) of the Code, section 716(a)-(d) of ERISA, and section 2799A-1(a)-(d) of the PHS Act. A plan that has chosen to opt into a state law must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into a specified state law, identify the state (or states), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law.

Currently, there are four states that allow self-insured plans to opt in: Nevada, New Jersey, Washington, and Virginia. According to the Nevada Department of Health and Human Services' 2020 Annual Report, 20 private entities or organizations have elected to participate in the state's balance billing law. In addition, according to the Virginia State Corporation Commission, 231 private self-insured plans in Virginia have elected to participate in the state's balance billing law.²⁰⁸ Furthermore, according to Washington's Office of the Insurance Commissioner, 309 private self-insured plans in Washington have elected to participate in the state's balance billing law.²⁰⁹ DOL does not have data on the number of self-insured plans that have opted into New Jersey's balance billing law. In order to estimate the number of self-insured plans that have opted into the balance billing law for New Jersey, DOL has scaled Washington's

²⁰⁸ Virginia State Corporation Commission. <https://scc.virginia.gov/balancebilling#>

²⁰⁹ Washington's Office of Insurance Commissioner. "Self-Funded Group Health Plans Participating in the Balance Billing Protection Act." <https://www.insurance.wa.gov/self-funded-group-health-plans>

estimate by the number of participants with self-insured ERISA-covered plans.²¹⁰ According to the 2019 Health Insurance Coverage Bulletin, there are respectively, 0.7 million, 2.1 million, and 2.7 million with self-insured ERISA-covered plans in Nevada, Virginia, and New Jersey. Additionally, according to the Washington’s Office of Insurance Commissioner, about 0.5 million self-insured participants have opted into Washington’s balance billing law.²¹¹ This results in a total of 6 million participants.²¹² Thus, DOL estimates that 20, 231, 309, and 57 private self-insured plans will opt in respectively in Nevada, Virginia, Washington, and New Jersey, resulting in a total of 617 self-insured plans.²¹³ These plans will incur the one-time burden and cost to include the disclosure in their plan documents in 2022.

DOL estimates that it will take 1 hour for an administrative assistant, with a wage rate of \$55.14, to gather information and review information.²¹⁴ This results in hour burden of 617 hours, with an equivalent cost of \$34,023. DOL estimates that it will take 30 minutes for a benefits manager, with a wage rate of \$134.21, to gather information and review information.²¹⁵ This results in hour burden of 309 hours, with an equivalent cost of \$41,406. In 2022, the total hour burden is 926 hours, with an equivalent cost of \$75,430.

The average number of participants in a self-insured ERISA-covered plan that will opt into the four states’ balance billing laws is 9,724.²¹⁶ DOL assumes that only printing and material

²¹⁰ Nevada Department of Health and Human Services’ Office of Consumer Health Assistance. “Payment for Medically Necessary Emergency Services Provided Out-of-Network 2020 Annual Report.” (2020). <https://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/Programs/CHA/AB469%20LCB%20Annual%20Report%202020.pdf>

²¹¹ Washington’s Office of Insurance Commissioner. “Self-Funded Group Health Plans Participating in the Balance Billing Protection Act.” <https://www.insurance.wa.gov/self-funded-group-health-plans>

²¹² Employee Benefits Security Administration. “Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2019 Annual Social and Economic Supplement to the Current Population Survey.” (2019). <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2019.pdf>

²¹³ New Jersey: $335 \times (0.5/2.7) = 62$ self-insured plans; 62 self-insured plans – 5 non-federal self-insured plans = 57 private self-insured plans

²¹⁴ For more information on how the Department estimates labor costs see: <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>

²¹⁵ For more information on how the Department estimates labor costs see: <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>

²¹⁶ $(6,000,000 \text{ participants with self-insured ERISA-covered plans}) / 617 \text{ self-insured ERISA-covered plans} = 9,724$ participants per self-insured ERISA-covered plan

costs are associated with the disclosure requirement, because the notice can be incorporated into existing plan documents. DOL estimates that the disclosure will require one-half of a page, at a cost of \$0.05 per page for printing and materials, and 34 percent of plan documents will be delivered electronically at minimal cost.²¹⁷ Thus, in 2022, the cost to deliver 66 percent of these disclosures in print is estimated to be approximately \$321.²¹⁸

Thus, the 3-year average hour burden is 309 hours, with an equivalent cost of \$25,143. The 3-year average cost burden is \$107.

5. ICRs Regarding Plan and Issuer Disclosure on Patient Protections Against Balance Billing

Section 9820(c) of the Code, section 720(c) of ERISA, and section 2799A-5(c) of the PHS Act require plans and issuers to make publicly available, post on a public website of the plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 9816 of the Code, section 716 of ERISA, and section 2799A-1 of the PHS Act apply, information in plain language on the provisions in these sections, and sections 2799B-1 and 2799B-2 of the PHS Act, and other applicable state laws on out-of-network balance billing, and information on contacting appropriate state and federal agencies in the case that an individual believes that such a provider or facility has violated the prohibition against balance billing.

As discussed earlier in HHS' PRA section, the total burden for all issuers and TPAs will be 6,153 hours with an equivalent cost of \$699,245 in 2021. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. HHS will account for approximately 3,077 hours with an equivalent cost of approximately \$349,622. DOL and the Treasury Department

²¹⁷ 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>.

²¹⁸ 9,724 participants x 0.66 x \$0.05 = \$321

will each account for approximately 1,539 hours with an equivalent cost of approximately \$174,811.

Starting in 2022, the total burden for all issuers and TPAs is estimated to be 558,778 hours with an equivalent cost of \$21,714,111. The total printing and materials cost for sending 33,526,677 notices by mail will be \$1,676,334 annually. As HHS, DOL, and the Treasury Department share jurisdiction, it is estimated that 50 percent of the burden will be accounted for by the HHS, 25 percent of the burden will be accounted for by the Treasury Department, and the remaining 25 percent will be accounted for by DOL. Thus, HHS will account for 279,389 hours, with an equivalent cost of \$10,857,056, and printing and materials cost of \$838,167 starting in 2022. DOL and the Treasury Department will each account for 139,695 hours with an equivalent cost of \$419,084.

Thus, the 3-year average hour burden associated with this requirement for DOL and the Treasury Department is 93,643 hours each with an equivalent cost of \$7,354,578. The 3-year average cost burden for DOL and Treasury is \$279,389 each.

The summary of burden below encompasses the following ICRs: (1) Information to be Shared about the QPA (26 CFR 54.9816-6T(d), 29 CFR 2590.716-6(d)), (2) Complaints Process for Surprise Medical Bills (26 CFR 54.9816-7T, 29 CFR 2590.716-7), (3) Opt-In State Balance Bill Process (26 CFR 54.9816-3T, 29 CFR 2590.716-3), and (4) Plan and Issuer Disclosure on Patient Protections Against Balance Billing.

Summary of Burden

Type of Review: New Collection.

Agency: DOL–EBSA, Treasury

Title: No Surprise Billing

OMB Numbers: 1210-NEW, 1545-NEW

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

Total Respondents: DOL- 1,985; Treasury- 1,779

Total Responses: DOL- 10,368,277; Treasury- 10,368,071

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 927,652 (DOL- 463,980, Treasury- 463,672)

Estimated Total Annual Burden Cost: \$558,885 (DOL- \$279,496, Treasury- \$279, 389)

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), (5 U.S.C. 601 *et seq.*), requires agencies to analyze options for regulatory relief of small entities to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” 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. Individuals and states are not included in the definition of a small entity. These interim final rules are not preceded by a general notice of proposed rulemaking, and thus the requirements of RFA do not apply.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule or any final rule for which a general notice of proposed rulemaking was published that includes any Federal mandate that may result in expenditures in any 1 year by state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately \$158 million. These interim final rules were not preceded by a general notice of proposed rulemaking, and thus the requirements of UMRA do not apply.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by federal agencies in formulating and implementing policies that have “substantial direct effects” on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the interim final rules.

These interim final rules protect participants, beneficiaries, or enrollees in group health plans and group and individual health insurance coverage, and covered individuals in FEHB plans, 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. A number of states currently have laws related to surprise medical bills. The Departments are of the view that Congress did not intend to supplant state laws regarding balance billing, but rather to supplement such laws. The provisions in these interim final rules are consistent with the statute’s general approach of supplementing state law. In addition, the No Surprises Act and these interim final rules recognize states’ traditional role as the primary regulators of health insurance issuers, providers, and facilities. The No Surprises Act authorizes states to enforce the new requirements regarding health insurance coverage, including those related to balance billing, with respect to issuers, providers, facilities, and providers of air ambulance services, with HHS enforcing only in cases where the state has notified HHS that the state does not have the authority to enforce or is not otherwise enforcing, or HHS has made a determination that a state has failed to substantially enforce the requirements.

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 a state-by-state basis. In addition, the Departments consulted with the NAIC, as required by the No Surprises Act, to establish the geographic regions to be used in the methodology for calculating the QPA.

OPM concluded that it would be inappropriate for FEHB plans to adopt varying state standards, and consistent with the FEHBA, it would adopt state laws where appropriate pursuant to bilaterally negotiated FEHB contracts.

While developing these interim final rules, the Departments attempted to balance the states' interests in regulating health insurance issuers, providers, and facilities with the need to ensure at least the minimum federal consumer protections in every state. By doing so, the Departments complied with the requirements of Executive Order 13132.

I. Congressional Review Act

These interim final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and to the Comptroller General for review in accordance with such provisions.

Statutory Authority

The Office of Personnel Management regulations are adopted pursuant to the authority contained in 5 U.S.C. 8902(p) and 5 U.S.C. 8913.

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002, 1135, 1182, 1185d, 1191a, 1191b, and 1191c; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, 2792, 2794, 2799A-1 through 2799B-9 of the PHS Act (42 U.S.C. 300gg-300gg-63, 300gg-91, 300gg-92, 300gg-94, 300gg-300gg139), as amended; sections 1311 and 1321 of the ACA (42 U.S.C. 13031 and 18041).

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.

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 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

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 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

Laurie Bodenheimer,

Associate Director
Healthcare and Insurance
Office of Personnel Management.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Mark J. Mazur,

Acting Assistant Secretary of the Treasury (Tax Policy).

Ali Khawar

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 amends 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.

Subpart A - Administration and General Provisions

2. Section 890.107 is amended by adding paragraph (e) to read as follows:

§ 890.107 Court review.

* * * * *

(e) A suit for equitable relief founded on 5 U.S.C. chapter 89 that is based on 5 U.S.C. 8902(p) and is governed by 5 CFR part 890 must be brought against OPM by December 31 of the 3rd year after the year in which disputed services were rendered.

3. Section 890.114 is added to subpart A to read as follows:

§ 890.114 Surprise billing.

(a) A carrier must comply with requirements described in 26 CFR 54.9816-3T through 54.9816-6T, 54.9817-1T, and 54.9822-1T, 29 CFR 2590.716-3 through 2590.716-6, 2590.717-1, and 2590.722, and 45 CFR 149.30, 149.110 through 149.140, and 149.310 in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage, subject to 5 U.S.C. 8902(m)(1), and the provisions of the carrier's contract. For purposes of application of such sections, all carriers are deemed to offer health benefits in the large group market.

(b) For purposes of the provisions referenced in paragraph (a) of this section:

Group health plan or plan shall mean a "health benefits plan" defined at 5 U.S.C. 8901(6), which is a Federal governmental plan offered pursuant to 5 U.S.C. chapter 89.

Health insurance issuer or issuer shall include a carrier defined at 5 U.S.C. 8901(7).

Where the carrier for a health benefits plan is a voluntary association, an association of organizations or entities, or is otherwise comprised of multiple entities, each entity is responsible for compliance in the same manner as such sections apply to group health plans and issuers. If and to the extent an entity offering a health benefits plan under 5 U.S.C. chapter 89 is licensed

under state law and is properly considered an issuer as defined at section 2791 of the Public Health Service Act, the entity is considered a carrier to the extent of its FEHB health benefits plan contractual and regulatory compliance.

Participant, beneficiary, or enrollee shall include an “enrollee” or “covered individual” as defined by 5 CFR 890.101, as appropriate.

(c) When a complaint challenges a carrier’s action or inaction with respect to the surprise billing provisions, OPM will coordinate with the Departments of Health and Human Services, Labor, and the Treasury to resolve the complaint.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 4. The authority citation for part 54 continues to read, in part, as follows:

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

* * * * *

Par. 5. Section 54.9801-1T is added to read as follows:

§ 54.9801-1T Basis and scope (temporary).

(a) *Statutory basis.* This section and §§ 54.9801-2 through 54.9801-6, 54.9802-1, 54.9802-2, 54.9802-3T, 54.9802-4, 54.9811-1, 54.9812-1, 54.9815-1251, 54.9815-2704, 54.9815-2705, 54.9815-2708, 54.9815-2711, 54.9815-2712, 54.9815-2713, 54.9815-2713A, 54.9815-2714, 54.9815-2715, 54.9815-2715A1, 54.9815-2715A2, 54.9815-2715A3, 54.9815-2719, 54.9815-2715A, 54.9816-1 through 9816-7, 54.9831-1, and 54.9833-1 implement Chapter 100 of Subtitle K of the Internal Revenue Code of 1986.

(b) *Scope.* A group health plan or health insurance issuer offering group health insurance coverage may provide greater rights to participants and beneficiaries than those set forth in the portability and market reform sections of this part. This part sets forth minimum requirements for

group health plans and group health insurance issuers offering group health insurance coverage concerning certain consumer protections of the Health Insurance Portability and Accountability Act (HIPAA), including special enrollment periods and the prohibition against discrimination based on a health factor, as amended by the Patient Protection and Affordable Care Act (Affordable Care Act). Other consumer protection provisions, including other protections provided by the Affordable Care Act, the Mental Health Parity and Addiction Equity Act, and the No Surprises Act are set forth in this part.

(c) *Similar requirements under the Employee Retirement Income Security Act and the Public Health Service Act.* Sections 701, 702, 703, 711, 712, 716, 717, 732, and 733 of the Employee Retirement Income Security Act of 1974 and sections 2701, 2702, 2704, 2705, 2721, 2791, 2799A-1, and 2799A-2 of the Public Health Service Act impose requirements similar to those imposed under Chapter 100 of Subtitle K with respect to health insurance issuers offering group health insurance coverage. *See* 29 CFR part 2590 and 45 CFR parts 144, 146, 148, and 149. *See* also part B of Title XXVII of the Public Health Service Act and 45 CFR parts 148 and 149 for other rules applicable to health insurance offered in the individual market (defined in § 54.9801-2).

Par. 6. Section 54.9801-2T is added to read as follows:

§ 54.9801-2T Definitions (temporary).

Unless otherwise provided, the definitions in this section and § 54.9801-2 govern in applying the provisions of sections 9801 through 9825 and 9831 through 9834.

Affiliation period means a period of time that must expire before health insurance coverage provided by an HMO becomes effective, and during which the HMO is not required to provide benefits.

COBRA definitions:

(1) *COBRA* means title X of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(2) *COBRA continuation coverage* means coverage, under a group health plan, that satisfies an applicable COBRA continuation provision.

(3) *COBRA continuation provision* means section 4980B (other than paragraph (f)(1) of section 4980B insofar as it relates to pediatric vaccines), sections 601-608 of ERISA, or title XXII of the PHS Act.

(4) *Exhaustion of COBRA continuation coverage* means that an individual's COBRA continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An individual is considered to have exhausted COBRA continuation coverage if such coverage ceases—

(i) Due to the failure of the employer or other responsible entity to remit premiums on a timely basis;

(ii) When the individual no longer resides, lives, or works in the service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other COBRA continuation coverage available to the individual; or

(iii) When the individual incurs a claim that would meet or exceed a lifetime limit on all benefits and there is no other COBRA continuation coverage available to the individual.

Condition means a *medical condition*.

Creditable coverage means *creditable coverage* within the meaning of §54.9801-4(a).

Dependent means any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant.

Employee Retirement Income Security Act of 1974 (ERISA) means the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*).

Enroll means to become covered for benefits under a group health plan (that is, when coverage becomes effective), without regard to when the individual may have completed or filed any forms that are required in order to become covered under the plan. For this purpose, an individual who has health coverage under a group health plan is enrolled in the plan regardless of whether the individual elects coverage, the individual is a dependent who becomes covered as a result of an election by a participant, or the individual becomes covered without an election.

Enrollment date means the first day of coverage or, if there is a waiting period, the first day of the waiting period. If an individual receiving benefits under a group health plan changes benefit packages, or if the plan changes group health insurance issuers, the individual's enrollment date does not change.

Excepted benefits means the benefits described as excepted in §54.9831(c).

First day of coverage means, in the case of an individual covered for benefits under a group health plan, the first day of coverage under the plan and, in the case of an individual covered by health insurance coverage in the individual market, the first day of coverage under the policy or contract.

Genetic information has the meaning given the term in §54.9802-3T(a)(3).

Group health insurance coverage means health insurance coverage offered in connection with a group health plan. Individual health insurance coverage reimbursed by the arrangements

described in 29 CFR 2510.3-1(l) is not offered in connection with a group health plan, and is not group health insurance coverage, provided all the conditions in 29 CFR 2510.3-1(l) are satisfied.

Group health plan or plan means a *group health plan* within the meaning of §54.9831-1(a).

Group market means the market for health insurance coverage offered in connection with a group health plan. (However, certain very small plans may be treated as being in the *individual market*, rather than the group market; see the definition of individual market in this section.)

Health insurance coverage means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage, individual health insurance coverage, and short-term, limited-duration insurance. However, benefits described in §54.9831(c)(2) are not treated as benefits consisting of medical care.

Health insurance issuer or issuer means an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA). Such term does not include a group health plan.

Health maintenance organization or HMO means—

(1) A federally qualified health maintenance organization (as defined in section 1301(a) of the PHS Act);

(2) An organization recognized under State law as a health maintenance organization; or

(3) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

Individual health insurance coverage means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited-duration insurance. Individual health insurance coverage can include dependent coverage.

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan. Unless a State elects otherwise in accordance with section 2791(e)(1)(B)(ii) of the PHS Act, such term also includes coverage offered in connection with a group health plan that has fewer than two participants who are current employees on the first day of the plan year.

Issuer means a *health insurance issuer*.

Late enrollee means an individual whose enrollment in a plan is a late enrollment.

Late enrollment means enrollment of an individual under a group health plan other than on the earliest date on which coverage can become effective for the individual under the terms of the plan; or through special enrollment. (For rules relating to special enrollment, see §54.9801-6.) If an individual ceases to be eligible for coverage under a plan, and then subsequently becomes eligible for coverage under the plan, only the individual's most recent period of eligibility is taken into account in determining whether the individual is a late enrollee under the plan with respect to the most recent period of coverage. Similar rules apply if an individual again becomes eligible for coverage following a suspension of coverage that applied generally under the plan.

Medical care has the meaning given such term by section 213(d), determined without regard to section 213(d)(1)(C) and so much of section 213(d)(1)(D) as relates to qualified long-term care insurance.

Medical condition or condition means any condition, whether physical or mental, including, but not limited to, any condition resulting from illness, injury (whether or not the injury is accidental), pregnancy, or congenital malformation. However, genetic information is not a condition.

Participant means *participant* within the meaning of section 3(7) of ERISA.

Placement, or being placed, for adoption means the assumption and retention of a legal obligation for total or partial support of a child by a person with whom the child has been placed in anticipation of the child's adoption. The child's placement for adoption with such person ends upon the termination of such legal obligation.

Plan year means the year that is designated as the plan year in the plan document of a group health plan, except that if the plan document does not designate a plan year or if there is no plan document, the plan year is—

(1) The deductible or limit year used under the plan;

(2) If the plan does not impose deductibles or limits on a yearly basis, then the plan year is the policy year;

(3) If the plan does not impose deductibles or limits on a yearly basis, and either the plan is not insured or the insurance policy is not renewed on an annual basis, then the plan year is the employer's taxable year; or

(4) In any other case, the plan year is the calendar year.

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or

individual health insurance coverage (or other coverage provided to federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

Public health plan means *public health plan* within the meaning of §54.9801-4(a)(1)(ix).

Public Health Service Act (PHS Act) means the Public Health Service Act (42 U.S.C. 201, *et seq.*).

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 1, excluding the heading “Notice 1,” with any additional information required by applicable state law:

NOTICE 1:

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

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 2, excluding the heading “Notice 2,” with any additional information required by applicable state law:

NOTICE 2:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage.

(4) If a court holds the 36-month maximum duration provision set forth in paragraph (1) of this definition or its applicability to any person or circumstances invalid, the remaining provisions and their applicability to other people or circumstances shall continue in effect.

Significant break in coverage means a *significant break in coverage* within the meaning of §54.9801-4(b)(2)(iii).

Special enrollment means enrollment in a group health plan under the rights described in §54.9801-6 or in group health insurance coverage under the rights described in 29 CFR 2590.701-6 or 45 CFR 146.117.

State health benefits risk pool means a *State health benefits risk pool* within the meaning of §54.9801-4(a)(1)(vii).

Travel insurance means insurance coverage for personal risks incident to planned travel, which may include, but is not limited to, interruption or cancellation of trip or event, loss of baggage or personal effects, damages to accommodations or rental vehicles, and sickness, accident, disability, or death occurring during travel, provided that the health benefits are not offered on a stand-alone basis and are incidental to other coverage. For this purpose, the term travel insurance does not include major medical plans that provide comprehensive medical protection for travelers with trips lasting 6 months or longer, including, for example, those working overseas as an expatriate or military personnel being deployed.

Waiting period means *waiting period* within the meaning of §54.9815-2708(b).

Par. 7. Section 54.9815-2719AT is added to read as follows:

§ 54.9815-2719AT Patient protections (temporary).

(a) – (b) [Reserved]

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning before January 1, 2022. *See also* §§ 54.9816-4T through 54.9816-7T, 54.9817-1T, and 54.9822-1T for rules applicable with respect to plan years beginning on or after January 1, 2022.

Par. 8. Sections 54.9816-1T, 54.9816-2T, 54.9816-3T, 54.9816-4T, 54.9816-5T, 54.9816-6T, 54.9816-7T, 54.9817-1T, and 54.9822-1T are added to read as follows:

Sec.

54.9816-1T Basis and scope (temporary).

54.9816-2T Applicability (temporary).
54.9816-3T Definitions (temporary).
54.9816-4T Preventing surprise medical bills for emergency services (temporary).
54.9816-5T Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities (temporary).
54.9816-6T Methodology for calculating qualifying payment amount (temporary).
54.9816-7T Complaints process for surprise medical bills regarding group health plans (temporary).
54.9817-1T Preventing surprise medical bills for air ambulance services (temporary).
54.9822-1T Choice of health care professional (temporary).

* * * * *

§ 54.9816-1T Basis and scope (temporary).

(a) *Basis.* This section and §§ 54.9816-2T through 54.9816-7T, 54.9817-1T, and 54.9822-1T implement subchapter B of chapter 100 of the Internal Revenue Code of 1986.

(b) *Scope.* This part establishes standards for group health plans with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 54.9816-2T Applicability (temporary).

(a) *In general.* The requirements in §§ 54.9816-4T through 54.9816-7T, 54.9817-1T, and 54.9822-1T apply to group health plans (including grandfathered health plans as defined in § 54.9815-1251T), except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 54.9816-4T through 54.9816-7T, 54.9817-1T, and 54.9822-1T do not apply to the following:

- (1) Excepted benefits as described in § 54.9831-1(c).
- (2) Short-term, limited-duration insurance as defined in § 54.9801-2.
- (3) Health reimbursement arrangements or other account-based group health plans as described in § 54.9815-2711(d).

§ 54.9816-3T Definitions (temporary).

The definitions in § 54.9801-2T apply to §§ 54.9816-4T through 54.9816-7T, 54.9817-1T, and 54.9822-1T unless otherwise specified. In addition, for purposes of §§ 54.9816-4T through 54.9816-7T, 54.9817-1T, and 54.9822-1T, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in § 54.9816-4T(c)(1).

Emergency services has the meaning given the term in § 54.9816-4T(c)(2).

Health care facility, with respect to a group health plan, in the context of non-emergency services, is each of the following:

- (1) A hospital (as defined in section 1861(e) of the Social Security Act);
- (2) A hospital outpatient department;
- (3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and
- (4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

- (1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and

(2) Provides any emergency services as described in § 54.9816-4T(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 54.9816-4T(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan, with respect to the furnishing of an item or service under the plan.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan, with respect to the furnishing of an item or service under the plan.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§ 54.9816-4T, 54.9816-5T, and 54.9817-1T are provided or covered, a written notice from the plan to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in 29 CFR 2560.503-1.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan under § 54.9816-4T(b)(3)(iv)(A), §

54.9816-5T(c)(3), or § 54.9817-1T(b)(4)(i); 29 CFR 2590.716-4(b)(3)(iv)(A), 2590.716-5(c)(3), or 2590.717-1(b)(4)(i); or 45 CFR 149.110(b)(3)(iv)(A), 149.120(c)(3), or 149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A-1(c) or 2799A-2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 54.9816-4T(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan. A single case agreement between an emergency facility and a plan that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan setting forth the terms and conditions on which a relevant item or service is provided to a participant or

beneficiary under the plan. A single case agreement between a health care facility and a plan that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in § 54.9816-6T(a)(13).

Service code has the meaning given the term in § 54.9816-6T(a)(14).

Qualifying payment amount has the meaning given the term in § 54.9816-6T(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with § 54.9816-6T); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts into such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

§ 54.9816-4T Preventing surprise medical bills for emergency services (temporary).

(a) *In general.* If a group health plan provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan payment must be made in accordance with the timing requirement described in section 9816(c)(6), or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant or beneficiary with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the Public Health Service Act) (as applicable) applied under the plan (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in § 54.9801-2).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an

independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.* (A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(1) For which benefits are provided or covered under the plan; and

(2) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant or beneficiary is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in 45 CFR 149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9816-5T Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities (temporary).

(a) *In general.* If a group health plan provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant or beneficiary by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of 45 CFR 149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan payment must be made in accordance with the timing requirement described in section 9816(c)(6) or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant or beneficiary toward any in-network deductible and in-network out-of-pocket maximums (including the annual

limitation on cost sharing under section 2707(b) of the Public Health Service Act) (as applicable) applied under the plan (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9816-6T Methodology for calculating qualifying payment amount (temporary).

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan, used to supplement the network of the plan for a specific participant or beneficiary in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in § 54.9815-2715A1.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—

(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

- (i) An emergency department of a hospital; or
- (ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan, the first year after 2019 for which coverage for such item or service is offered under that plan.

(6) *First sufficient information year* means, with respect to a group health plan —

(i) In the case of an item or service for which the plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan has sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan for which the plan has sufficient

information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in § 54.9815-2711(d)(6)(i), and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan, but that is offered under the plan in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan consistent with the plan's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan uses to determine a participant's or beneficiary's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan must—

(A) Calculate separate median contracted rates for CPT code modifiers “26” (professional component) and “TC” (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.* (i) If a plan has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) Methodology for calculation of the qualifying payment amount—(1) In general. (i)

For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI-U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:
 $(\text{CPI-U } 2019 / \text{CPI-U } 2018) \times (\text{CPI-U } 2020 / \text{CPI-U } 2019) \times (\text{CPI-U } 2021 / \text{CPI-U } 2020)$

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will

calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as $\text{CPI-U present year} / \text{CPI-U prior year}$.

(iii) For anesthesia services furnished during 2022, the plan must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan must then

multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(vii) For any other items or services for which a plan generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans.* With respect to a sponsor of a group health plan in a geographic region in which the sponsor did not offer any group health plan during 2019—

(i) For the first year in which the group health plan is offered in such region—

(A) If the plan has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan must calculate the qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan and furnished during the first year; and

(B) If the plan does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan is offered in the region, the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the

first coverage year for such item or service with respect to such plan or coverage if the plan does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan through use of any eligible database, and then increasing that rate by the percentage increase in the CPI-U over such preceding year. For purposes of this section, in cases in which an eligible database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan), the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan, the plan must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in

applying such paragraph to such item or service, the reference to ‘furnished during 2022’ is treated as a reference to furnished during such first sufficient information year, the reference to ‘in 2019’ is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan, the plan must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2023 or a subsequent year’ is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan), the plan must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan reimburses for the item or service billed under the new service code compared to the rate that the plan reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With an initial payment or notice of denial of payment under § 54.9816-4T, § 54.9816-5T, or § 54.9817-1T:

(i) The qualifying payment amount for each item or service involved;

(ii) A statement to certify that, based on the determination of the plan—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iii) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(iv) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code; and

(iv) If applicable, a statement that the plan's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan is responsible for any costs associated with accessing such database.

(f) *Audits.* See 45 CFR 149.140(f) for audit procedures that apply with respect to ensuring that a plan is in compliance with the requirement of applying a qualifying payment amount under §§ 54.9816-4T, 54.9816-5T, 54.9817-1T, and this section, and ensuring that such amount so applied satisfies the requirements under this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9816-7T Complaints process for surprise medical bills regarding group health plans (temporary).

See 45 CFR 149.150 for the process to receive and resolve complaints that a specific group health plan may be failing to meet the requirement of applying a qualifying payment amount under §§ 54.9816-4T, 54.9816-5T, 54.9816-6T, and 54.9817-1T, which may warrant an investigation.

§ 54.9817-1T Preventing surprise medical bills for air ambulance services (temporary).

(a) *In general.* If a group health plan provides or covers any benefits for air ambulance services, the plan must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with § 54.9816-6T) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the Public Health Service Act) (as applicable) applied under the plan (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan payment must be made in accordance with the timing requirement

described in section 9817(b)(6), or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 54.9822-1T Choice of health care professional (temporary).

(a) *Choice of health care professional—(1) Designation of primary care provider—(i) In general.* If a group health plan, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example*, the plan has satisfied the requirements of this paragraph (a).

(2) *Designation of pediatrician as primary care provider—(i) In general.* If a group health plan requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan and is available to accept the child. In such a case, the plan must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(2) *Conclusion.* In this *Example 1*, the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish

allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(2) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access.* A group health plan described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan may require such a professional to agree to otherwise adhere to the plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan is described in this paragraph (a)(3) if the plan—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(2) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaining gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that *A* seeks gynecological services from *C*, an out-of-network provider.

(2) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(2) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(2) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider—(i) In general.* If a group health plan requires the designation by a participant or beneficiary of a primary care provider, the plan must provide a notice informing each participant of the terms of the plan regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan provides a participant with a summary plan description or other similar description of benefits under the plan.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans that require or allow for the designation of primary care providers by participants or beneficiaries, insert:

[Name of group health plan] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator] at [insert contact information].

(B) For plans that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS.

9. The authority citation for part 2590 is revised 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).

10. Section 2590.715-2719A is amended by revising paragraph (c) to read as follows:

§ 2590.715-2719A Patient protections.

* * * * *

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning before January 1, 2022. *See also* §§ 2590.716-4 through 2590.716-7, 2590.717-1, and 2590.722 of this part for rules applicable with respect to plan years beginning on or after January 1, 2022.

Subpart D [Redesignated as Subpart E]

11. Redesignate subpart D as subpart E and add a new subpart D to read as follows:

Subpart D-Surprise Billing and Transparency Requirements

Sec.

2590.716-1 Basis and scope.

2590.716-2 Applicability.

2590.716-3 Definitions.

2590.716-4 Preventing surprise medical bills for emergency services.

2590.716-5 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

2590.716-6 Methodology for calculating qualifying payment amount.

2590.716-7 Complaints process for surprise medical bills regarding group health plans and group health insurance coverage.

2590.717-1 Preventing surprise medical bills for air ambulance services.

2590.722 Choice of health care professional.

Subpart D-Surprise Billing and Transparency Requirements

§ 2590.716-1 Basis and scope.

(a) *Basis.* Sections 2590.716-1 through 2590.722 implement section 716-722 of ERISA.

(b) *Scope.* This part establishes standards for group health plans and health insurance issuers offering group health insurance coverage with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 2590.716-2 Applicability.

(a) *In general.* The requirements in §§ 2590.716-4 through 2590.716-7, 2590.717-1, and 2590.722 apply to group health plans and health insurance issuers offering group health insurance coverage (including grandfathered health plans as defined in § 2590.715-1251), except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 2590.716-4 through 2590.716-7, 2590.717-1, and 2590.722 do not apply to the following:

(1) Excepted benefits as described in § 2590.732.

(2) Short-term, limited-duration insurance as defined in § 2590.701-2.

(3) Health reimbursement arrangements or other account-based group health plans as described in § 2590.715-2711(d).

§ 2590.716-3 Definitions.

The definitions in this part apply to §§ 2590.716 through 2590.722, unless otherwise specified. In addition, for purposes of §§ 2590.716 through 2590.722, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant or beneficiary is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage.

Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in § 2590.716-4(c)(1).

Emergency services has the meaning given the term in § 2590.716-4(c)(2).

Health care facility, with respect to a group health plan or group health insurance coverage, in the context of non-emergency services, is each of the following:

- (1) A hospital (as defined in section 1861(e) of the Social Security Act);
- (2) A hospital outpatient department;
- (3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and
- (4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

- (1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and
- (2) Provides any emergency services as described in § 2590.716-4(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 2590.716-4(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group health insurance

coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan or group health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§ 2590.716-4, 2590.716-5, and 2590.717-1 are provided or covered, a written notice from the plan or issuer to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan or coverage and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in § 2560.503-1 of this chapter.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan or issuer under 26 CFR 54.9816-4T(b)(3)(iv)(A), 54.9816-5T(c)(3), or 54.9817-1T(b)(4)(i); § 2590.716-4(b)(3)(iv)(A), § 2590.716-5(c)(3), or § 2590.717-1(b)(4)(i); or 45 CFR 149.110(b)(3)(iv)(A),

149.120(c)(3), or 149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan or issuer enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A-1(c) or 2799A-2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 2590.716-4(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan or coverage, respectively. A single case agreement between an emergency facility and a plan or issuer that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan or

coverage, respectively. A single case agreement between a health care facility and a plan or issuer that is used to address unique situations in which a participant or beneficiary requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary under the plan or coverage, respectively.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in § 2590.716-6(a)(13).

Service code has the meaning given the term in § 2590.716-6(a)(14).

Qualifying payment amount has the meaning given the term in § 2590.716-6(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with § 2590.716-6); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan or group health insurance coverage offered by a health insurance issuer to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of ERISA). A group health plan that opts into such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

§ 2590.716-4 Preventing surprise medical bills for emergency services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan or issuer—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan or coverage and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan or coverage payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 716(c)(6) of ERISA, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant or beneficiary with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in § 2590.701-2).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an

independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.* (A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(1) For which benefits are provided or covered under the plan or coverage; and

(2) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant or beneficiary is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in 45 CFR 149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.716-5 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

(a) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan or issuer must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant or beneficiary by a nonparticipating provider with respect to a visit at a participating health care facility, unless

the provider has satisfied the notice and consent criteria of 45 CFR 149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan or issuer—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan or coverage and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan or coverage payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 716(c)(6) of ERISA, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant or beneficiary toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.716-6 Methodology for calculating qualifying payment amount.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant or beneficiary in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in § 2590.715-2715A1.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—

(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is

treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

- (i) An emergency department of a hospital; or
- (ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan or group health insurance coverage offered by a health insurance issuer, the first year after 2019 for which coverage for such item or service is offered under that plan or coverage.

(6) *First sufficient information year* means, with respect to a group health plan or group health insurance coverage offered by a health insurance issuer—

(i) In the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan or issuer has sufficient

information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in § 2590.715-2711(d)(6)(i), and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan or group health insurance coverage offered by a health insurance issuer, but that is offered under the plan or coverage in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan or health insurance issuer offering group health insurance coverage has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year —

(A) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan or health insurance issuer offering group health insurance coverage, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's or beneficiary's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all group health insurance coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated

with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan or issuer must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by such issuer that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan or issuer must—

(A) Calculate separate median contracted rates for CPT code modifiers “26” (professional component) and “TC” (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.* (i) If a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan or issuer has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount—(1) In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan or issuer must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI-U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:
 $(\text{CPI-U } 2019 / \text{CPI-U } 2018) \times (\text{CPI-U } 2020 / \text{CPI-U } 2019) \times (\text{CPI-U } 2021 / \text{CPI-U } 2020)$

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as $\text{CPI-U present year} / \text{CPI-U prior year}$.

(iii) For anesthesia services furnished during 2022, the plan or issuer must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan or issuer must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan or issuer.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant or beneficiary to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan or issuer must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan or issuer.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant or beneficiary to determine the qualifying payment amount.

(vii) For any other items or services for which a plan or issuer generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan or issuer must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans and coverage.* With respect to a sponsor of a group health plan or health insurance issuer offering group health insurance coverage in a geographic region in which the sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(i) For the first year in which the group health plan or group health insurance coverage, respectively, is offered in such region—

(A) If the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan or issuer must calculate the

qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan or coverage and furnished during the first year; and

(B) If the plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan or issuer must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan or group health insurance coverage, respectively, is offered in the region, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan or issuer does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan or issuer, respectively, through use of any eligible database, and then increasing that rate by the percentage increase in the CPI-U over such preceding year. For purposes of this section, in cases in which an eligible

database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan or issuer must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2022’ is treated as a reference to furnished during such first sufficient information year, the reference to ‘in 2019’ is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2023 or a subsequent year’ is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan or issuer reimburses for the item or service billed under the new service code compared to the rate that the plan or issuer reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan or issuer must

calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan or issuer must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With each initial payment or notice of denial of payment under § 2590.716-4, § 2590.716-5, or § 2590.717-1 of this part:

(i) The qualifying payment amount for each item or service involved;

(ii) A statement to certify that, based on the determination of the plan or issuer—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's or beneficiary's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iii) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the

30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(iv) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code;

(iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan or issuer that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan or issuer is responsible for any costs associated with accessing such database.

(f) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.716-7 Complaints process for surprise medical bills regarding group health plans and group health insurance coverage.

(a) *Scope and definitions*—(1) *Scope*. This section establishes a process to receive and resolve complaints regarding information that a specific group health plan or health insurance issuer offering group health insurance coverage may be failing to meet the requirements under subpart D of this part, which may warrant an investigation.

(2) *Definitions*. In this section—

(i) *Complaint* means a communication, written or oral, that indicates there has been a potential violation of the requirements under subpart D of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process*. (1) DOL will consider the date a complaint is filed to be the date upon which DOL receives an oral or written statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) DOL will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. DOL will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaint resolution process. As part of the response, DOL may request additional information needed to process the complaint. Such additional information may include:

(i) Explanations of benefits;

(ii) Processed claims;

(iii) Information about the health care provider, facility, or provider of air ambulance services involved;

(iv) Information about the group health plan or health insurance issuer covering the individual;

(v) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(vi) The summary plan description, policy, certificate, contract of insurance, membership booklet, outline of coverage, or other evidence of coverage the plan or issuer provides to participants or beneficiaries;

(vii) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(viii) Any other information DOL may need to make a determination of facts for an investigation.

(3) DOL will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by DOL. A complaint is considered processed after DOL has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint and the plan or issuer involved, DOL may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if DOL receives a complaint where another entity has enforcement jurisdiction over the plan or issuer;

(iii) Refer the plan or issuer for an investigation for enforcement action; or

(iv) Provide the complainant with an explanation of the resolution of the complaint and any corrective action taken.

§ 2590.717-1 Preventing surprise medical bills for air ambulance services.

(a) *In general.* If a group health plan or a health insurance issuer offering group health insurance coverage provides or covers any benefits for air ambulance services, the plan or issuer

must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with § 2590.716-6) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan or issuer must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan or coverage and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan or coverage payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network

rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 717(b)(6) of ERISA, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.722 Choice of health care professional.

(a) *Choice of health care professional—(1) Designation of primary care provider—(i) In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan

designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider—(i) In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(2) *Conclusion.* In this *Example 1*, the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(2) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access.* A group health plan, or a health insurance issuer offering group health insurance coverage, described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including

a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(2) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaining gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that *A* seeks gynecological services from *C*, an out-of-network provider.

(2) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(2) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(2) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider—(i) In general.* If a group health plan or health insurance issuer requires the designation by a participant or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant (in the

individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, or beneficiaries, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A, Subchapter B

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 147, 149, and 156 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

12. The authority citation for part 144 is revised 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.

13. Section 144.101 is amended by:

- a. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively; and
- b. Adding new paragraph (d).

The addition reads as follows:

§ 144.101 Basis and purpose.

* * * * *

(d) Part 149 of this subchapter implements the provisions of parts D and E of title XXVII of the PHS Act that apply to group health plans, health insurance issuers in the group and individual markets, health care providers and facilities, and providers of air ambulance services.

* * * * *

14. Section 144.102 is revised to read as follows:

§ 144.102 Scope and applicability.

(a) For purposes of 45 CFR parts 144 through 149, all health insurance coverage is generally divided into two markets—the group market and the individual market. The group market is further divided into the large group market and the small group market.

(b) The protections afforded under 45 CFR parts 144 through 149 to individuals and employers (and other sponsors of health insurance offered in connection with a group health plan) are determined by whether the coverage involved is obtained in the small group market, the large group market, or the individual market.

(c) Coverage that is provided to associations, but not related to employment, and sold to individuals is not considered group coverage under 45 CFR parts 144 through 149. If the coverage is offered to an association member other than in connection with a group health plan, the coverage is considered individual health insurance coverage for purposes of 45 CFR parts 144 through 149. The coverage is considered coverage in the individual market, regardless of whether it is considered group coverage under state law. If the health insurance coverage is offered in connection with a group health plan as defined at 45 CFR 144.103, it is considered group health insurance coverage for purposes of 45 CFR parts 144 through 149.

(d) Provisions relating to CMS enforcement of parts 146, 147, 148, and 149 are contained in part 150 of this subchapter.

15. Section 144.103 is amended by revising the introductory text to read as follows:

§ 144.103 Definitions.

For purposes of parts 146 (group market), 147 (group and individual market), 148 (individual market), 149 (surprise billing and transparency), and 150 (enforcement) of this subchapter, the following definitions apply unless otherwise provided:

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

16. The authority citation for part 147 is revised 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, and section 3203, Pub. L. 116-136, 134 Stat. 281.

17. Section 147.138 is amended by revising paragraph (c) to read as follows:

§ 147.138 Patient protections.

* * * * *

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning before January 1, 2022. *See also* subparts B and D of part 149 of this subchapter for rules applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

18. Add part 149 to read as follows:

PART 149 – SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

Subpart A – General Provisions

Sec.

149.10 Basis and scope.

149.20 Applicability.

149.30 Definitions.

Subpart B – Protections against Balance Billing for the Group and Individual Health Insurance Markets

149.110 Preventing surprise medical bills for emergency services.

149.120 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

149.130 Preventing surprise medical bills for air ambulance services.

149.140 Methodology for calculating qualifying payment amount.

149.150 Complaints process for surprise medical bills regarding group health plans and group and individual health insurance coverage.

Subpart C – [Reserved]

Subpart D – Additional Patient Protections

149.310 Choice of health care professional.

Subpart E – Health Care Provider, Health Care Facility, and Air Ambulance Service Provider Requirements

149.410 Balance billing in cases of emergency services.

149.420 Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating health care facilities.

149.430 Provider and facility disclosure requirements regarding patient protections against balance billing.

149.440 Balance billing in cases of air ambulance services.

149.450 Complaints process for balance billing regarding providers and facilities.

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

Subpart A – General Provisions

§ 149.10 Basis and scope.

(a) *Basis.* This part implements parts D and E of title XXVII of the PHS Act.

(b) *Scope.* This part establishes standards for group health plans, health insurance issuers offering group or individual health insurance coverage, health care providers and facilities, and providers of air ambulance services with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 149.20 Applicability.

(a) *In general.* (1) The requirements in subparts B 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.

(2) The requirements in subpart E of this part apply to health care providers, health care facilities, and providers of air ambulance services.

(b) *Exceptions.* The requirements in subparts B and D of this part do not apply to the following:

(1) Excepted benefits as described in §§ 146.145 and 148.220 of this subchapter.

(2) Short-term, limited-duration insurance as defined in § 144.103 of this subchapter.

(3) Health reimbursement arrangements or other account-based group health plans as described in § 147.126(d) of this subchapter.

§ 149.30 Definitions.

The definitions in part 144 of this subchapter apply to this part, unless otherwise specified. In addition, for purposes of this part, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in § 149.110(c)(1).

Emergency services has the meaning given the term in § 149.110(c)(2).

Health care facility, with respect to a group health plan or group or individual health insurance coverage, in the context of non-emergency services, is each of the following:

- (1) A hospital (as defined in section 1861(e) of the Social Security Act);
- (2) A hospital outpatient department;
- (3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and
- (4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

(1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and

(2) Provides any emergency services as described in § 149.110(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 149.110(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§ 149.110 through 149.130 are provided or covered, a written notice from the plan or issuer to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan or coverage and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in 29 CFR 2560.503-1.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan or issuer under 26 CFR 54.9816-4T(b)(3)(iv)(A), 54.9816-5T(c)(3), or 54.9817-1T(b)(4)(i); 29 CFR 2590.716-4(b)(3)(iv)(A), 2590.716-5(c)(3), or 2590.717-1(b)(4)(i); or § 149.110(b)(3)(iv)(A), § 149.120(c)(3), or § 149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan or issuer enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A-1(c) or 2799A-2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 149.110(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a

relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between an emergency facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between a health care facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in § 149.140(a)(13).

Service code has the meaning given the term in § 149.140(a)(14).

Qualifying payment amount has the meaning given the term in § 149.140(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with § 149.140); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage offered by a health insurance issuer to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts in to such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and

services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

Subpart B – Protections Against Balance Billing for the Group and Individual Health Insurance Markets

§ 149.110 Preventing surprise medical bills for emergency services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan or issuer—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan or coverage and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan or coverage payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A-1(c)(6) of the PHS Act, or in

cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant, beneficiary, or enrollee with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in § 144.103 of this subchapter).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health

of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.* (A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(1) For which benefits are provided or covered under the plan or coverage; and

(2) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in § 149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date*. The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.120 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

(a) *In general*. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan or issuer must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described*. The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant, beneficiary, or enrollee by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of § 149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements*. In the case of items and services described in paragraph (b) of this section, the plan or issuer—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or

All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan or coverage and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan or coverage payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A-1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant, beneficiary, or enrollee toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.130 Preventing surprise medical bills for air ambulance services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits for air ambulance services,

the plan or issuer must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with § 149.140) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan or issuer must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan or coverage and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan or coverage payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network

rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A-2(b)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.140 Methodology for calculating qualifying payment amount.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in § 147.210 of this subchapter.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—

(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this

paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

- (i) An emergency department of a hospital; or
- (ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, the first year after 2019 for which coverage for such item or service is offered under that plan or coverage.

(6) *First sufficient information year* means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(i) In the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in paragraph (b)

of this section in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in § 147.126(d)(6)(i) of this subchapter, and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, but that is offered under the plan or coverage in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan or health insurance issuer offering group or individual health insurance coverage has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all group or individual health insurance coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated

with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan or issuer must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by such issuer that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan or issuer must—

(A) Calculate separate median contracted rates for CPT code modifiers “26” (professional component) and “TC” (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.* (i) If a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan or issuer has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount—(1) In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan or issuer must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI-U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:
 $(\text{CPI-U } 2019 / \text{CPI-U } 2018) \times (\text{CPI-U } 2020 / \text{CPI-U } 2019) \times (\text{CPI-U } 2021 / \text{CPI-U } 2020)$

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI-U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI-U for each calendar year is the average of the CPI-U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as $\text{CPI-U present year} / \text{CPI-U prior year}$.

(iii) For anesthesia services furnished during 2022, the plan or issuer must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan or issuer must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan or issuer.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan or issuer must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan or issuer.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(vii) For any other items or services for which a plan or issuer generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan or issuer must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans and coverage.* With respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage in a geographic region in which the sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(i) For the first year in which the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region—

(A) If the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan or issuer must calculate the

qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan or coverage and furnished during the first year; and

(B) If the plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan or issuer must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in the region, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan or issuer does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan or issuer, respectively, through use of any eligible database, and then increasing that rate by the percentage increase in the CPI-U over such preceding year. For purposes of this section, in cases in which an eligible

database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan or issuer must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2022’ is treated as a reference to furnished during such first sufficient information year, the reference to ‘in 2019’ is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to ‘furnished during 2023 or a subsequent year’ is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan or issuer reimburses for the item or service billed under the new service code compared to the rate that the plan or issuer reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan or issuer must

calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI-U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan or issuer must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With each initial payment or notice of denial of payment under § 149.110, § 149.120, or § 149.130:

(i) The qualifying payment amount for each item or service involved;

(ii) A statement to certify that, based on the determination of the plan or issuer—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iii) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the

30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(iv) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code; and

(iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan or issuer that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan or issuer is responsible for any costs associated with accessing such database.

(f) *Audits.* The procedures described in part 150 of this subchapter apply with respect to ensuring that a plan or coverage is in compliance with the requirement of applying a qualifying

payment amount under this subpart and ensuring that such amount so applied satisfies the requirements under this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.150 Complaints process for surprise medical bills regarding group health plans and group and individual health insurance coverage.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process to receive and resolve complaints regarding information that a specific group health plan or health insurance issuer offering group or individual health insurance coverage may be failing to meet the requirements under this subpart, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written or oral, that indicates there has been a potential violation of the requirements under subpart B of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral or written statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. As part of the response, HHS may request additional information needed to process the complaint. Such additional information may include:

(i) Explanations of benefits;

(ii) Processed claims;

(iii) Information about the health care provider, facility, or provider of air ambulance services involved;

(iv) Information about the group health plan or health insurance issuer covering the individual;

(v) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(vi) The summary plan description, policy, certificate, contract of insurance, membership booklet, outline of coverage, or other evidence of coverage the plan or issuer provides to participants, beneficiaries, or enrollees;

(vii) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(viii) Any other information HHS may need to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination.

Based on the nature of the complaint and the plan or issuer involved, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the plan or issuer;

(iii) Refer the plan or issuer for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of the resolution of the complaint and any corrective action taken.

Subpart C – [Reserved]

Subpart D – Additional Patient Protections

§ 149.310 Choice of health care professional.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider—(i) In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(2) *Conclusion.* In this *Example 1*, the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(2) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and

gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(2) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaining gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that *A* seeks gynecological services from *C*, an out-of-network provider.

(2) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(2) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(2) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider—(i) In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Subpart E—Health Care Provider, Health Care Facility, and Air Ambulance Service

Provider Requirements

§ 149.410 Balance billing in cases of emergency services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is furnished emergency services (for which benefits are provided under the plan or coverage) with respect to an emergency medical condition with respect to a visit at an emergency department of a hospital or an independent freestanding emergency department—

(1) A nonparticipating emergency facility must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for such emergency services (as defined in 26 CFR 54.9816-4T(c)(2), 29 CFR 2590.716-4(c)(2), and § 149.110(c)(2), as applicable) that exceeds the cost-sharing requirement for such services (as determined in accordance with 26 CFR 54.9816-4T(b)(3)(ii) and (iii), 29 CFR 2590.716-4(b)(3)(ii) and (iii), and § 149.110(b)(3)(ii) and (iii), as applicable).

(2) A nonparticipating provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for an emergency service (as defined in 26 CFR 54.9816-4T(c)(2), 29 CFR 2590.716-4(c)(2), and § 149.110(c)(2), as applicable) furnished to such individual by such provider with respect to such emergency medical condition and visit for which the individual receives emergency services at the hospital or independent freestanding emergency department that exceeds the cost-sharing requirement for such service (as determined

in accordance with 26 CFR 54.9816-4T(b)(3)(ii) and (iii), 29 CFR 2590.716-4(b)(3)(ii) and (iii), and § 149.110(b)(3)(ii) and (iii), as applicable).

(b) *Notice and consent to be treated by a nonparticipating provider or nonparticipating emergency facility.* The requirements in paragraph (a) of this section do not apply with respect to items and services described in 26 CFR, 54.9816-4T(c)(2)(ii)(A), 29 CFR 2590.716-4(c)(2)(ii)(A), § 149.110(c)(2)(ii)(A), as applicable, and are not included as emergency services if all of the following conditions are met:

(1) The attending emergency physician or treating provider determines that the participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into account the individual's medical condition. The attending emergency physician's or treating provider's determination is binding on the facility for purposes of this requirement.

(2) The provider or facility furnishing such additional items and services satisfies the notice and consent criteria of § 149.420(c) through (g) with respect to such items and services, provided that the written notice additionally satisfies paragraphs (b)(2)(i) and (ii) of this section, as applicable. In applying this paragraph (b)(2), a reference in § 149.420 to a nonparticipating provider is deemed to include a nonparticipating emergency facility.

(i) In the case of a participating emergency facility and a nonparticipating provider, the written notice must also include a list of any participating providers at the facility who are able to furnish such items and services involved and notification that the participant, beneficiary, or enrollee may be referred, at their option, to such a participating provider.

(ii) In the case of a nonparticipating emergency facility, the written notice must include the good faith estimated amount that the participant, beneficiary, or enrollee may be charged for items or services furnished by the nonparticipating emergency facility or by nonparticipating providers with respect to the visit at such facility (including any item or service that is reasonably

expected to be furnished by the nonparticipating emergency facility or nonparticipating providers in conjunction with such items or services).

(3) The participant, beneficiary, or enrollee (or an authorized representative of such individual) is in a condition to receive the information described in § 149.420, as determined by the attending emergency physician or treating provider using appropriate medical judgment, and to provide informed consent under such section, in accordance with applicable State law. For purposes of this section and § 149.420, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee.

(4) The provider or facility satisfies any additional requirements or prohibitions as may be imposed under State law.

(c) *Inapplicability of notice and consent exception to certain items and services.* A nonparticipating provider or nonparticipating facility specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider or nonparticipating emergency facility satisfied the notice and consent criteria in § 149.420(c) through (g).

(d) *Retention of certain documents.* A nonparticipating emergency facility (with respect to such facility or any nonparticipating provider at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage (or an authorized representative of such an individual) a written consent in accordance with § 149.420(e), with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, the provider may either

coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(e) *Notification to plan or issuer.* In the case of a participant, beneficiary, or enrollee who is stabilized and furnished additional items and services described in § 149.110(c)(2)(ii), a nonparticipating provider or nonparticipating emergency facility must notify the plan or issuer, respectively, when transmitting the bill for such items and services, either on the bill or in a separate document, as to whether all of the conditions described in paragraph (b) of this section are met with respect to each of the items and services for which the bill is submitted, and if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraph (b)(2) of this section.

(f) *Applicability date.* The provisions of this section are applicable with respect to emergency services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.420 Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating health care facilities.

(a) *In general.* A nonparticipating provider of a group health plan or group or individual health insurance coverage who provides items or services (other than emergency services) for which benefits are provided under the plan or coverage at a participating health care facility must not bill, and must not hold liable, a participant, beneficiary, or enrollee of such plan or coverage for a payment amount for such an item or service furnished by such provider with respect to a visit at the facility that exceeds the cost-sharing requirement for such item or service (as determined in accordance with 26 CFR 54.9816-5T(c)(1) and (2), 29 CFR 2590.717-1(c)(1) and (2), and § 149.120(c)(1) and (2), as applicable), unless the provider (or the participating health care facility on behalf of the provider) satisfies the notice and consent criteria of paragraph (c) of this section.

(b) *Inapplicability of notice and consent exception to certain items and services.* The notice and consent criteria in paragraphs (c) through (i) of this section do not apply, and a nonparticipating provider specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to the following services:

(1) Ancillary services, meaning—

(i) Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner;

(ii) Items and services provided by assistant surgeons, hospitalists, and intensivists;

(iii) Diagnostic services, including radiology and laboratory services; and

(iv) Items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility.

(2) Items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider satisfied the notice and consent criteria in paragraph (c) of this section.

(c) *Notice and consent to be treated by a nonparticipating provider.* Subject to paragraph (f) of this section, and unless prohibited by State law, a nonparticipating provider satisfies the notice and consent criteria of this paragraph (c) with respect to items or services furnished by the provider to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage, if the provider (or a participating health care facility on behalf of a nonparticipating provider)—

(1) Provides to the participant, beneficiary, or enrollee a written notice in paper or, as practicable, electronic form, as selected by the individual, that contains the information required under paragraph (d) of this section, provided such written notice is provided:

(i) In accordance with guidance issued by HHS, and in the form and manner specified in such guidance;

(ii) With the consent document, and is provided physically separate from other documents and not attached to or incorporated into any other document; and

(iii) To such participant, beneficiary, or enrollee—

(A) Not later than 72 hours prior to the date on which the individual is furnished such items or services, in the case where the appointment to be furnished such items or services is scheduled at least 72 hours prior to the date on which the individual is to be furnished such items and services; or

(B) On the date the appointment to be furnished such items or services is scheduled, in the case where the appointment is scheduled within 72 hours prior to the date on which such items or services are to be furnished. Where an individual is provided the notice on the same date that the items or services are to be furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements apply.

(2) Obtains from the participant, beneficiary, or enrollee the consent described in paragraph (e) of this section to be treated by the nonparticipating provider. An authorized representative may receive the notice on behalf of a participant, beneficiary, or enrollee, and may provide consent on behalf of the participant, beneficiary, or enrollee. For purposes of this section and § 149.410, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. The consent must—

(i) Be provided voluntarily, meaning the individual is able to consent freely, without undue influence, fraud, or duress;

(ii) Be obtained in accordance with, and in the form and manner specified in, guidance issued by HHS; and

(iii) Not be revoked, in writing, by the participant, beneficiary, or enrollee prior to the receipt of items and services to which the consent applies.

(3) Provides a copy of the signed written notice and consent to the participant, beneficiary, or enrollee in-person or through mail or email, as selected by the participant, beneficiary, or enrollee.

(d) *Information required under written notice.* The written notice described in paragraph (c)(1) of this section must be provided in the form and manner specified by HHS in guidance, and must—

(1) State that the health care provider is a nonparticipating provider, with respect to the health plan or coverage.

(2) Include the good faith estimated amount that such nonparticipating provider may charge the participant, beneficiary, or enrollee for the items and services involved (including any item or service that is reasonably expected to be furnished by the nonparticipating provider in conjunction with such items or services), including notification that the provision of the estimate or consent to be treated under paragraph (e) of this section does not constitute a contract with respect to the charges estimated for such items and services or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility.

(3) Provide a statement that prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility.

(4) Clearly state that consent to receive such items and services from such nonparticipating provider is optional and that the participant, beneficiary, or enrollee may instead seek care from an available participating provider, with respect to the plan or coverage, as applicable, and that in such cases the cost-sharing responsibility of the participant, beneficiary, or enrollee would not exceed the responsibility that would apply with respect to such an item or service that is furnished by a participating provider, as applicable, with respect to such plan.

(e) *Consent described to be treated by a nonparticipating provider.* The consent described in this paragraph (e), with respect to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage who is to be furnished items or services by a nonparticipating provider, must be documented on a form specified by the Secretary, in consultation with the Secretary of Labor, through guidance and provided in accordance with such guidance, that must be signed by the participant, beneficiary, or enrollee before such items and services are furnished and that –

(1) Acknowledges in clear and understandable language that the participant, beneficiary, or enrollee has been—

(i) Provided with the written notice under paragraph (c) of this section, in the form selected by the participant, beneficiary, or enrollee.

(ii) Informed that the payment of such charge by the participant, beneficiary, or enrollee might not accrue toward meeting any limitation that the plan or coverage places on cost sharing, including an explanation that such payment might not apply to an in-network deductible or out-of-pocket maximum applied under the plan or coverage.

(2) States that by signing the consent, the individual agrees to be treated by the nonparticipating provider and understands the individual may be balance billed and subject to cost-sharing requirements that apply to services furnished by the nonparticipating provider.

(3) Documents the time and date on which the participant, beneficiary, or enrollee received the written notice described in paragraph (c) of this section and the time and date on which the individual signed the consent to be furnished such items or services by such nonparticipating provider.

(f) *Language access.* (1) A nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) must provide the individual with the choice to receive the written notice and consent document in any of the 15 most common languages in the State in which the applicable facility is located, except that the notice and consent document may

instead be available in any of the 15 most common languages in a geographic region that reasonably reflects the geographic region served by the applicable facility; and

(2) If the individual's preferred language is not among the 15 most common languages in which the nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) makes the notice and consent document available and the individual cannot understand the language in which the notice and consent document are provided, the notice and consent criteria in paragraph (c) of this section are not met unless the nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) has obtained the services of a qualified interpreter to assist the individual with understanding the information contained in the notice and consent document.

(g) *Scope of consent.* The consent described in paragraph (e) of this section will constitute consent only to the receipt of the information provided pursuant to this section and will not constitute a contractual agreement of the participant, beneficiary, or enrollee to any estimated charge or amount included in such information, or to be treated by that provider or facility.

(h) *Retention of certain documents.* A participating health care facility (with respect to nonparticipating providers at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage a written consent in accordance with paragraph (e) of this section, with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, where the facility does not otherwise obtain the consent on behalf of the provider, the provider may either coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(i) *Notification to plan or issuer.* For each item or service furnished by a nonparticipating provider described in paragraph (a) of this section, the provider (or the participating facility on behalf of the nonparticipating provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility, and, if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraphs (c) and (e) of this section. In instances where, to the extent permitted by this section, the nonparticipating provider bills the participant, beneficiary, or enrollee directly, the provider may satisfy the requirement to notify the plan or issuer by including the notice with the bill to the participant, beneficiary, or enrollee.

(j) *Applicability date.* The provisions of this section are applicable with respect to items and services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.430 Provider and facility disclosure requirements regarding patient protections against balance billing.

(a) *In general.* Each health care provider and health care facility (including an emergency department of a hospital and an independent freestanding emergency department) must make publicly available, post on a public website of such provider or facility (if applicable), and provide to any individual who is a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer and to whom the provider or facility furnishes items or services, the information described in paragraph (b) of this section regarding patient protections against balance billing, except as provided in paragraphs (e) and (f) of this section. A provider or facility must make the disclosures in accordance with the method and timing requirements set forth in paragraphs (c) and (d) of this section.

(b) *Content.* The disclosures required under this section must include, in clear and understandable language, all the information described in this paragraph (b) (and may include any additional information that does not conflict with that information).

(1) A statement that explains the requirements of and prohibitions applicable to the health care provider or health care facility under sections 2799B-1 and 2799B-2 of the PHS Act and their implementing regulations in §§ 149.410 and 149.420;

(2) If applicable, a statement that explains any State law requirements regarding the amounts such provider or facility may, with respect to an item or service, charge a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer with respect to which such provider or facility does not have a contractual relationship, after receiving payment, if any, from the plan or coverage, respectively, for such item or service and any applicable cost-sharing payment from such participant, beneficiary, or enrollee; and

(3) A statement providing contact information for the appropriate State and Federal agencies that an individual may contact if the individual believes the provider or facility has violated a requirement described in the notice.

(c) *Required methods for disclosing information.* Health care providers and health care facilities must provide the disclosure required under this section as follows:

(1) With respect to the required disclosure to be posted on a public website, the information described in paragraph (b) of this section, or a link to such information, must appear on a searchable homepage of the provider's or facility's website. A provider or facility that does not have its own website is not required to make a disclosure under this paragraph (c)(1).

(2) With respect to the required disclosure to the public, a provider or facility must make public the information described in paragraph (b) of this section on a sign posted prominently at the location of the provider or facility. A provider that does not have a publicly accessible location is not required to make a disclosure under this paragraph (c)(2).

(3) With respect to the required disclosure to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a provider or facility must provide the information described in paragraph (b) of this section in a one-page (double-sided) notice, using print no smaller than 12-point font. The notice must be provided in-person or through mail or email, as selected by the participant, beneficiary, or enrollee.

(d) *Timing of disclosure to individuals.* A health care provider or health care facility is required to provide the notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer no later than the date and time on which the provider or facility requests payment from the individual, or with respect to an individual from whom the provider or facility does not request payment, no later than the date on which the provider or facility submits a claim to the group health plan or health insurance issuer.

(e) *Exceptions.* A health care provider is not required to make the disclosures required under this section—

(1) If the provider does not furnish items or services at a health care facility, or in connection with visits at health care facilities; or

(2) To individuals to whom the provider furnishes items or services, if such items or services are not furnished at a health care facility, or in connection with a visit at a health care facility.

(f) *Special rule to prevent unnecessary duplication with respect to health care providers.* To the extent a provider furnishes an item or service covered under the plan or coverage at a health care facility (including an emergency department of a hospital or independent freestanding emergency department), the provider satisfies the requirements of paragraphs (c)(2) and (3) of this section if the facility makes the information available, in the required form and manner, pursuant to a written agreement. Accordingly, if a provider and facility enter into a written

agreement under which the facility agrees to make the information required under this section available on a sign posted prominently at the facility and to provide the one-page notice to individuals in compliance with this section, and the facility fails to do so, then the facility, but not the provider, violates the disclosure requirements of this section.

(g) *Applicability date.* The provisions of this section are applicable beginning on January 1, 2022.

§ 149.440 Balance billing in cases of air ambulance services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer who is furnished air ambulance services (for which benefits are available under such plan or coverage) from a nonparticipating provider of air ambulance services, with respect to such plan or coverage, the provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for the air ambulance services furnished by the provider that is more than the cost-sharing amount for such service (as determined in accordance with 26 CFR 54.9817-1T(b)(1) and (2), 29 CFR 2590.717-1(b)(1) and (2), and § 149.130(b)(1) and (2), as applicable).

(b) *Applicability date.* The provisions of this section are applicable with respect to air ambulance services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.450 Complaint process for balance billing regarding providers and facilities.

(a) *Scope and definitions—(1) Scope.* This section establishes a process for HHS to receive and resolve complaints regarding information that a health care provider, provider of air ambulance services, or health care facility may be failing to meet the requirements under subpart E of this part, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written, or oral, that indicates there has been a potential violation of the requirements under this subpart, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral, written, or electronic statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. HHS may request additional information that may be needed to process the complaint as part of the response. Such additional information may include:

(i) Health care provider, air ambulance provider, or health care facility bills;

(ii) Health care provider, air ambulance provider, or health care facility network status;

(iii) Information regarding the participant's, beneficiary's, or enrollee's health care plan or health insurance coverage;

(iv) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(v) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(vi) Any other information HHS needs to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination.

Based on the nature of the complaint, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the health care provider, air ambulance provider or health care facility;

(iii) Refer the health care provider, air ambulance provider or health care facility for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of resolution and any corrective action taken.

PART 156 – HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

19. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

20. Section 156.155 is amended by:

a. Revising paragraph (a)(3);

b. Redesignating paragraph (c) as paragraph (d); and

c. Adding a new paragraph (c).

The revision and addition read as follows:

§ 156.155 Enrollment in catastrophic plans.

(a) * * *

(3) Provides coverage of the essential health benefits under section 1302(b) of the Affordable Care Act, except that the plan provides no benefits for any plan year (except as provided in paragraphs (a)(4), (b), and (c) of this section) until the annual limitation on cost sharing in section 1302(c)(1) of the Affordable Care Act is reached.

* * * * *

(c) *Coverage to prevent surprise medical bills.* A catastrophic plan must provide benefits as required under sections 2799A-1 and 2799A-2 of the Public Health Service Act and their implementing regulations in §§149.110, 149.120, and 149.130 or any applicable State law providing similar protections to individuals, and will not violate paragraph (a)(3) of this section solely because of the provision of such benefits before the annual limitation on cost sharing is reached.

* * * * *

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